



Piano

CLINICAL AUDIOMETER

USER MANUAL



PIANO

CLINICAL AUDIOMETER

USER MANUAL



Read this manual thoroughly before using the device. Pay particular attention to Chapter 1 ("Safety: warnings and information") and Chapter 3 ("Installation and power up").



Internal inspections and repairs must only be performed by authorised personnel.

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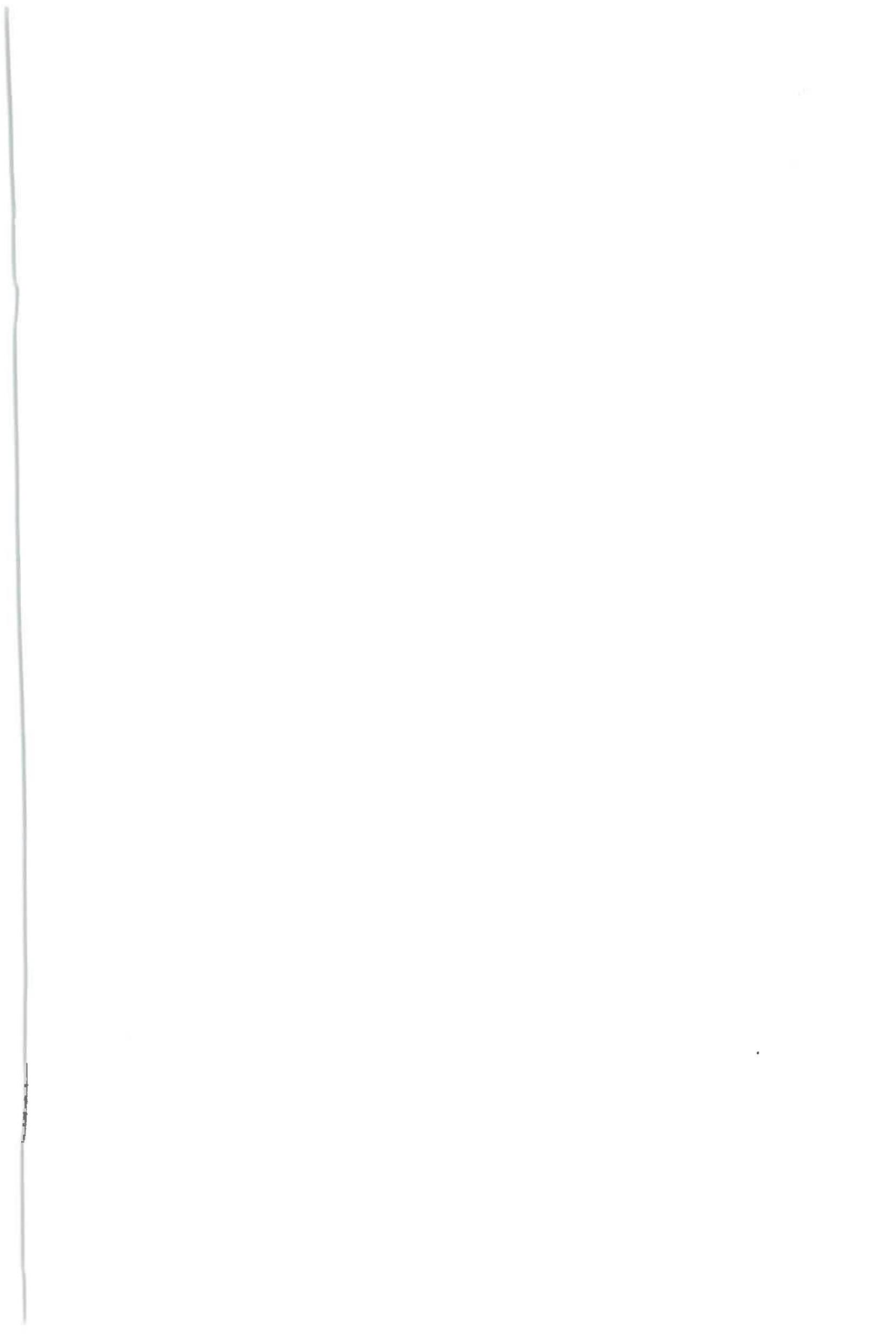
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Document title: ***AUIC-User Manual En***

Revision: **15**

Date: **2017.12.02**

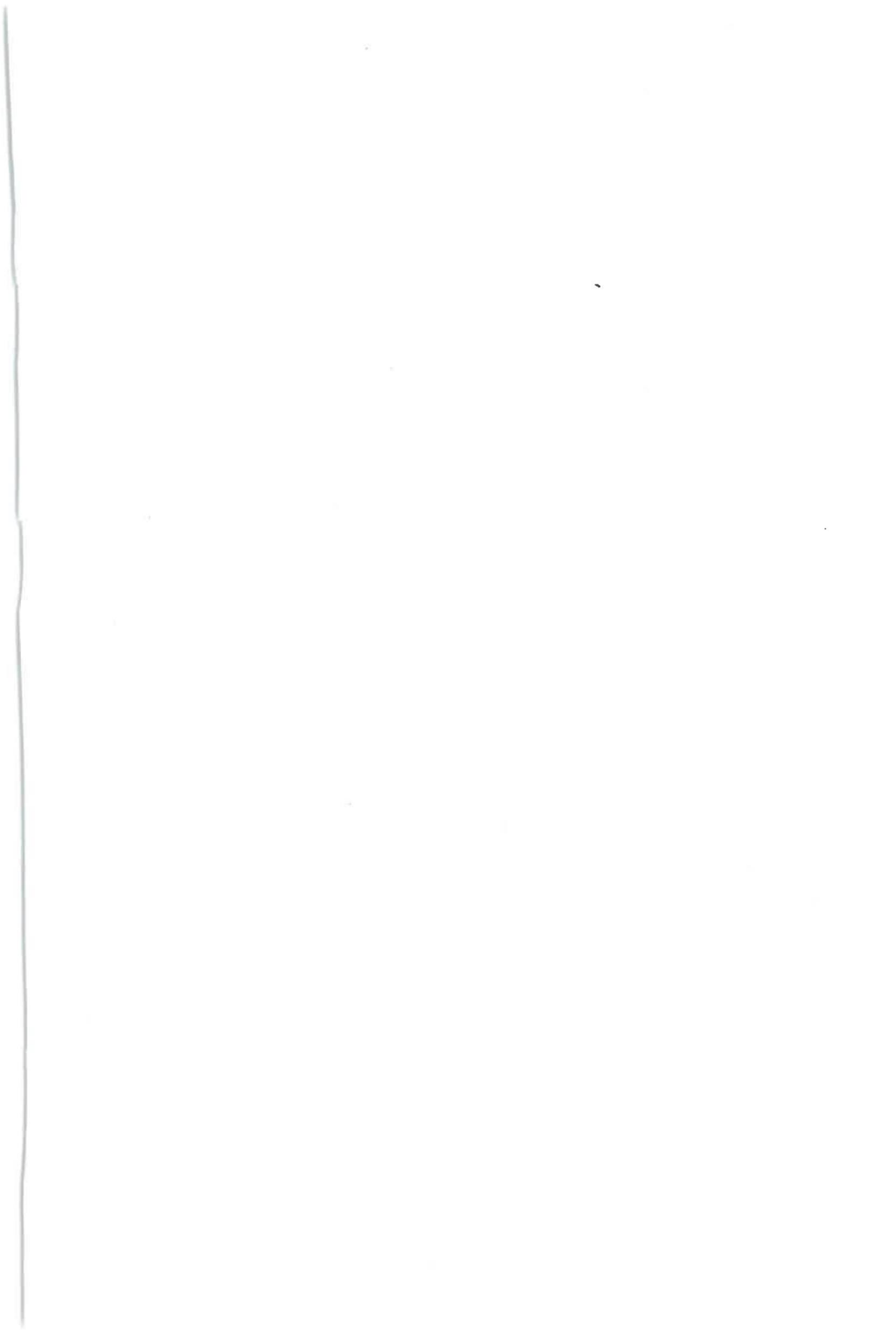


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Foreword

Thank you for purchasing an Inventis audiometer.

Piano audiometer offers a combination of features placing it at the top of the class of clinical audiometers. Two independent channels, a complete battery of tests, a wide colour graphical display with touch screen and the internal flash memory with the speech material are just some of the features herein described that make Piano the ideal device for the most demanding users.

For further information, and to report any problems of whatever description that may be encountered, contact the company at:



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CHAPTER 1:

Safety: warnings and information

OPERATOR MANUAL

We recommend that you read this manual thoroughly to obtain maximum efficiency and safety from your audiometer. It is particularly important that you read this chapter in its entirety. It contains essential warnings and important information on the safe and correct use of the instrument.

In this manual, the safety symbol shown below draws your attention to information that is particularly important for safe and correct use.



OPERATOR RESPONSIBILITIES

The Piano audiometer is guaranteed to work efficiently and reliably only if used according to the instructions and procedures given in this manual.

If the instrument ever develops a malfunction or requires repair, disconnect it from the electrical mains supply and do not use it again until the necessary repair and servicing have been completed. Defective and malfunctioning parts must only be replaced with original spare parts supplied by Inventis srl. All repairs must be performed exclusively by Inventis or by personnel authorised by Inventis.

No part of the instrument may be modified or replaced without the prior written authorisation of Inventis.

Users are entirely responsible for any malfunction caused by improper use, or by maintenance or repair operations performed by any party other than Inventis srl or an authorised Service Centre. Inventis srl and its Service Centres accept responsibility for the performance and reliability of the instrument only if:

1. all connections, adjustments, modifications and repairs are performed exclusively by personnel authorised by Inventis;
2. the installation's electrical power supply and ground connections comply with the applicable standards for electro-medical devices.

INTENDED USE

Piano audiometer is designed for use by audiology specialists in conducting pure-tone and speech audiometry tests, and certain of the more important supra-threshold tests.

Audiometric tests must be conducted in particularly quiet environment, and preferably in a soundproof booth. If these conditions cannot be provided, the patient should be given sound-isolating headphones to wear so that ambient and background noise can be blocked out as far as possible.

Piano audiometer is intended for use by persons who have a detailed knowledge of the procedures involved in conducting an audiometric test; the operator must therefore be either an audiologist (or a technician with knowledge and experience of audiometry) or a doctor in possession of specific skills (audiology specialist or occupational physician).

PRECAUTIONS

To ensure correct and safe use of the audiometer, the following precautions must be observed.

Installation and general precautions



Make certain that the required ambient conditions are met (during transport, storage and operation) as indicated in "APPENDIX A: Technical Specifications".



Piano audiometer will not be protected if exposed during use to flammable anaesthetic gases or similar products. Risk of explosion.



Avoid installing and using Piano audiometer close to any sources of strong electromagnetic field: these could interfere with the operation of the device.



Use only original accessories supplied by Inventis srl, unless specifically indicated otherwise.



Use only power adapters intended for medical equipment, certified to EN 60601-1. For further information, see "APPENDIX A: Technical Specifications".



Piano audiometer is a medical device: if connected to a computer (or any external device, such as a CD player) located within the "patient area" (as defined in EN 60601-1), this likewise must be a medical device, or protected by an isolating transformer, in order to ensure that the computer (external device) + audiometer combination is in compliance with EN standard 60601-1.



Piano audiometer can be used in conjunction with a soundproof booth to conduct tests under optimum acoustic conditions. Before connecting the audiometer to a soundproof booth, check that the sockets are compatible with the specifications prescribed for each connector.



Piano needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in Appendix E.



Use of portable and mobile RF communications equipment can affect the correct operation of Piano device. Make reference to the EMC information in the Appendix E.

Calibration



The calibration of the audiometer is valid only for the transducers supplied with the device. If a transducer is replaced, the audiometer must be recalibrated.



The calibration of the audiometer is valid for transducers supplied with the audiometer, if connected directly to the instrument, without any interposition of extension leads and without the passage from connectors to panel (as habitually occurs in soundproof booth installations). If the transducers are not connected directly to the audiometer, a new calibration procedure will be required before the instrument is used.



In each test window, when you select a not-calibrated transducer, the background of the 'output' area will be displayed in red colour. Moreover, you will not be able to send any stimulus through not-calibrated transducers.



Take note of the calibration interval indicated for the audiometer. Use of the instrument beyond the calibration interval expiry date can lead to unreliable diagnoses.

Hygiene



The eartips of ER-3 and ER-5 insert earphones are disposable, likewise that of the masking earphone; do not use the same eartip for different patients. Dispose of eartips after use.



Disinfect the cushions of headphones between one patient and the next, following the procedure described in *CHAPTER 12: Maintenance*.

Use



The audiometer can generate tones at an intensity potentially damaging to the patient. Take particular care to set the intensity of the tone correctly before it is presented.



The desktop microphone shall be placed at a distance not greater than 15 cm from the mouth to reduce the background noise

DISPOSAL

Like all electronic devices, your audiometer contains extremely small quantities of certain hazardous substances such as cadmium or mercury. If such substances are allowed to enter the normal waste disposal cycle without suitable preliminary treatment, they can cause damage to the environment and to health. All parts of the audiometer must therefore be disposed of separately.

At the end of its life, take (or have taken) the disused instrument to a civic waste disposal and recycling facility, or return it to the reseller against the purchase of an equivalent new instrument.

Separate waste collection and the subsequent operations of treatment, recycling and disposal facilitate the manufacture of new devices from recycled materials, limiting any negative impact on the environment and public health that might otherwise derive from improper disposal.

CONFORMITY

Piano audiometer is a class IIa medical device, according to Annex IX of Medical Device Directive (MDD) 93/42/EEC as amended by 2007/47/EC directive.

The leading company TÜV certified the Inventis Quality Management System as compliant to ISO 9001 and ISO 13485 standards.



SYMBOLS ON LABELS



Name and address of the manufacturer



Caution: specific warnings or precautions are associated with this device; consult the accompanying documents for a safe use.



Consult instruction for use.



Follow instructions for use



This symbol means this product is covered by the Directive 2012/19/EU on waste electrical and electronic equipment (WEEE). It is required not to dispose this product as unsorted municipal waste, but to collect it separately.



Device with applied parts of type BF (EN60601-1).



Product conforms to European Community Medical Device Directive (MMD) 93/42/EEC, as amended by 2007/47/EC directive. Class IIa device; number of notified body: 0123 (TÜV SÜD Product Service GmbH).

Rx only

Caution: Federal Law (USA) restricts this device to sale by or on the order of a licenced healthcare practitioner.

IP20 *IP (Ingress Protection) Code: this device is protected against the access of objects sized > 12.5 mm, not protected against liquid.*

REF *Catalogue number*

Serial number of the device. The number is made up of 13 alphanumeric characters indicating the model, series, year of manufacture and serial number. In particular, the number comprises these segments:

SN

- *first 5 characters: Inventis product code*
- *characters 6 and 7: year of manufacture ("10" denotes 2010)*
- *character 8: model series*
- *characters 9... 13: serial number*



UDI code

(01)08054187380099(21)AU†CD16200570

CHAPTER 2:

Introduction

This chapter describes the main features of the Inventis Piano audiometer, and in particular, explains the differences between the model Basic and Plus.

MAIN FEATURES

Despite its reduced size and weight, the features of Piano place it at the top of the class of clinical audiometers. The broad battery of tests and the supreme flexibility, conjugated with the extreme simplicity of use, make Piano the ideal choice for clinics and hospitals, as well as for professional practitioners who demand the very best from their instruments.

The main strengths of Piano audiometer are:

- two separate and independent channels;
- large and bright colour graphics display with touch screen;
- highly ergonomic keyboard layout, reflecting thorough research and extensive testing in the field;
- compact and intelligent design;
- many tests available;
- internal flash memory in which to store word lists used for speech audiometry;
- interaction with computer, using Maestro software.

Piano audiometer is available in 2 versions, *Basic* and *Plus*: compared to the Basic version, Piano Plus features High Frequency and Multi-frequency audiometry, Bekesy and MLD tests.

Piano is also available with the VRA (Visual Reinforcement Audiometry) option, which adds the paediatric audiometry to the test battery.

The following tables indicate the types of tests available on Piano audiometer.

Exam	Channel	Input	Output
PURE TONE AUDIOMETRY	Ch. 1	Pure tone, warble, NBN	AC, BC, FF
	Ch. 2	NBN, WN	AC, BC, FF, Insert
AUTO-THRESHOLD	Ch. 1	Pure tone	AC
SPEECH AUDIOMETRY	Ch. 1	EXT1, EXT2, MIC, INT1, INT2	AC, BC, FF
	Ch. 2	SN, WN, EXT1, EXT2, INT1, INT2	AC, BC, FF, Insert
ABLB	Ch. 1	Pure tone	AC
	Ch. 2	Pure tone	AC
MLB	Ch. 1	Pure tone	AC
	Ch. 2	Pure tone	AC
SISI	Ch. 1	Pure tone	AC, BC
	Ch. 2	NBN, WN	AC, BC, Insert
DLI	Ch. 1	Pure tone	AC, BC
	Ch. 2	NBN, WN	AC, BC, Insert
TONE DECAY	Ch. 1	Pure tone	AC, BC
	Ch. 2	NBN, WN	AC, BC, Insert
MASTER HEARING AID	Ch. 1	EXT1, EXT2, MIC, INT1, INT2	AC
	Ch. 2	EXT1, EXT2, MIC, INT1, INT2	AC
STENGER	Ch. 1	Pure tone, warble, EXT1, EXT2, MIC, INT1, INT2	AC

Exam	Channel	Input	Output
	Ch. 2	Pure tone, warble, EXT1, EXT2, MIC, INT1, INT2	AC
TEN TEST	Ch. 1	Pure tone	AC
	Ch. 2	TEN noise	AC
QuickSIN TEST	Ch. 1	INT1, INT2	AC, FF
	Ch. 2	INT1, INT2	AC, FF
<i>Only on Piano Plus</i>			
HIGH FREQUENCY AUDIOMETRY	Ch. 1	Pure tone, warble	AC, FF
	Ch. 2	NBN	AC, FF
MULTIFREQUENCY AUDIOMETRY	Ch. 1	Pure tone, warble	AC, BC, FF
	Ch. 2	NBN, WN	AC, BC, FF, Insert
BEKESY	Ch. 1	Pure tone	AC, BC
	Ch. 2	NBN, WN	AC, Insert
MLD	Ch. 1	Pure tone	VA
	Ch. 2	NBN, WN	VA
<i>Only with VRA option</i>			
PEDIATRIC AUDIOMETRY	Ch. 1	Pure tone, warble, NBN	AC, BC, FF
	Ch. 2	NBN, WN	AC, BC, FF, Insert

Input INT1 and INT2 denote the internal flash memory, in which audio files can be stored.

ACCESSORIES

The following table lists the various accessories either supplied with or obtainable to order for the Piano audiometers.

Part	Piano Basic	Piano Plus
Telephonics TDH-39 or RadioEar DD45 supra-aural headphones	●	●
Sennheiser HDA-200 or Sennheiser HDA-300 circum-aural headphones	-	●
Stereo to mono adapter for Sennheiser HDA-300	-	●
ER-5 insert earphones	opt.	opt.
ER- 3 insert earphones	opt.	opt.
Amplivox Audiocups noise excluding enclosures (fit only on TDH-39 and DD45 headphones)	opt.	opt.
B71 bone vibrator	●	●
IME-100 Insert masking earphone	opt.	opt.
Patient response switch	●	●
Additional patient response switch	opt.	opt.
Monitor headset with boom microphone	●	●
Clip-on microphone for patient-to-operator communication	●	●
Desktop microphone for live speech test	opt.	opt.
Integrated thermal printer	opt.	opt.
Plastic cover sheet	●	●
Soft carrying case	opt.	opt.
Inventis Software Suite	●	●
USB cable	●	●
Medical grade power supply (6V)	●	●
User manual	●	●
<i>Only with VRA option</i>		
Desktop response switch for children	●	●

CHAPTER 3:

Installation and power up

Whilst the installation of a Piano audiometer is a relatively simple procedure, it should be entrusted to a person with the requisite skills. If the installation is not performed correctly, the system could be affected by safety problems when in use.

This chapter describes the procedure for installing the system.



Keep the packaging materials, in case the audiometer should need to be sent to the dealer or to Inventis for any reason.

PRECAUTIONS

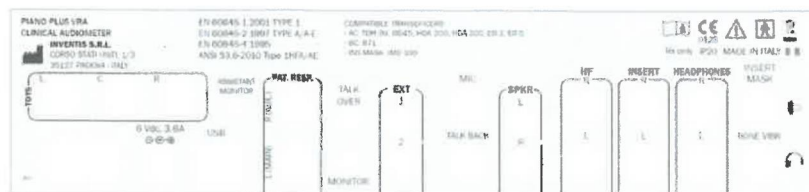
Like any other electric or electronic device, the Piano audiometer will emit electromagnetic waves. Even though its emissions are within the limits of standards, other electronic devices close to the audiometer might be affected, if particularly sensitive to electromagnetic interference.

Should this occur, check just by switching the audiometer OFF and ON and try to eliminate the interference using one or more of the following solutions:

- change the orientation and/or the position of the device affected by interference;
- distance the affected device from the audiometer;
- plug the affected device into a power socket on a circuit other than the circuit to which the audiometer is connected;
- consult the manufacturer or a service centre for assistance.

CONNECTIONS

All connection points for accessories are located on the rear panel, as also is the power switch. This section refers to the Piano Plus VRA model. The TOYS and ASSISTANT MONITOR connectors are available only for the VRA version. In the case of the Piano Basic audiometer, the HF connectors are not available.



Plug all transducers and accessories into the respective sockets as indicated in the following table:

Connector	Attachment
 INSERT MASK	Insert earphone for masking
 BONE VIBR.	Bone vibrator
HEADPHONES	Supra-aural headphones (TDH-39 or DD45): Right R and Left L
INSERT	Insert earphones (ER-3 or ER-5) for AC: Right R and Left L
HF	HF headphones (Sennheiser HDA-300 or Sennheiser HDA-200 with adapter).
SPKR	Free field speaker: Right R and Left L
MIC	Operator microphone for live speech tests
TALK BACK	Patient microphone
TALK OVER	Microphone for operator to patient communications or live speech test
MONITOR	Monitor headphones
EXT	External inputs 1 and 2 for speech audiometry with external audio source
 PATIENT RESP.	Left (L) and Right (R) patient response switches. If only one switch is available, use the L socket.
USB	USB cable for the connection to the PC
TOYS	Left (L) Central(C) and Right (R) toys connectors. Connect only Inventis TOY accessory.
ASSISTANT MONITOR	Assistant monitor headphones

Connect the power adapter to the  input and to the relative power cord, which should be plugged into an a.c. mains socket supplying the voltage indicated on the adapter label.



All connections must be made with the device switched off, that is to say with the power switch set to position 0.



Use only power adapters intended for medical equipment, certified to EN 60601-1. For further information, see "Appendix A – Technical Specifications".

POWER-UP AND MAIN SCREEN

Once all cables and leads are connected, the instrument can be switched on from the rear panel.

A few seconds after power-up, the display of the audiometer will show the main screen, illustrated below.

6 Feb 2014 17:51			
Pure Tone Audiometry		DLI	
Speech Audiometry		MLD	
Auto Threshold		Tone Decay	
Békésy		Stenger	
HF Audiometry		Master Hearing Aid	
Multifrequency		Pediatric Audiometry	
ABLB		TEN Test	
MLB		QuickSIN	
SISI			
AC transducer (LF): TDH 39			
SETUP		OK	

The main screen lists all the tests available on the audiometer; to conduct one of these, select it by turning the left-hand knob of the instrument to highlight the name, then press the OK function button (or touch the INTERRUPTER of channel 1).

The top part of the display shows the current date and time.

The bottom part of the display indicates the calibration expiry date (12 months subsequent to the date of the last calibration) and the transducer selected for an air conduction test at standard frequency (TDH-39 or DD45 headphones, HDA-200 or HDA-300 headphones – only for Piano Plus -, ER-3 or ER-5 insert type earphones).

The instrument can be configured in such a way as to skip the main screen and go straight to the pure-tone audiometry window: see *Chapter 11: Settings*.

CHAPTER 4:

Controls on Piano audiometer

This chapter describes the controls incorporated into the keyboard and touch screen of Piano audiometer.

THE TOUCH SCREEN

The Piano audiometer has a wide colour display, featuring a touch screen. Through the touch screen it is possible:

- controlling some of the exam settings, and
- moving through the windows of the user interface.

The touch sensitive areas of the display are identified with a yellow background.

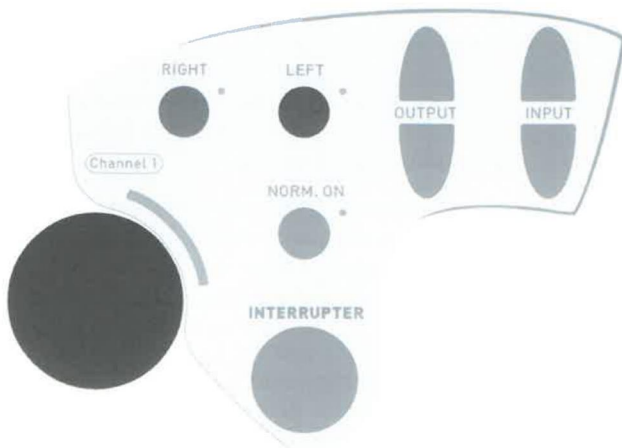
In the lower part of the display you will always find four (or more) yellow function buttons: simply touch them to access to the relevant function.

CONTROL OF CHANNELS

Piano audiometer has two separate and independent channels. This section describes the controls used to operate the two channels.

As default setting, Channel 1 is the main channel, i.e. the one used for the stimulus in pure tone audiometry, whereas Channel 2 is the secondary channel, used for masking. It is possible to invert the behaviour of the two channels through the Settings window (see *CHAPTER 11: Settings*). The following description assumes Channel 1 to be the main channel.

The controls for one channel are illustrated below (the layout is duplicated in mirror image for the other channel).



Right and Left. The Right and Left keys are used to select stimulation on either side. For stimulation on both sides, press the two keys simultaneously. By default, selecting one side as the stimulation side on channel 1, the opposite side is assigned automatically to channel 2; however, the operator can change the masking side, making it the same as the stimulation side.

Output. The Output buttons are used to select the transducer utilized, which can be one of various types, depending on the type of test and the channel:

- air conduction (AC –supra-aural headphones– / AC-INS –insert earphones– / AC-HF –circum-aural headphones, suitable for HF audiometry–)
- bone conduction (BC)
- free field (FF)
- insert type earphones for masking (INS).

Input. The Input buttons are used to select the input signal. Various signals can be used according to the type of test, the channel and the audiometer model.

For pure-tone audiometry, possible inputs are:

- channel 1: tone and warble;
- channel 2: narrow band noise (NBN) and white noise (WN).

For speech audiometry, possible inputs are:

- channel 1: external signals 1 or 2 (EXT1, EXT2), internal flash memory signals 1 or 2 (INT1, INT2) and external microphone (MIC);
- channel 2: external signals 1 or 2 (EXT1, EXT2), internal flash memory signals 1 or 2 (INT1, INT2), speech noise (SN) and white noise (WN).

Interrupter. This key switches on the channel. To eliminate any possible mechanical switch noise completely — as this could influence the response

of the patient — the designers of the product opted for a capacitive touch button: the operator need only touch the metal cap to present the tone. In the Piano audiometer, three different modes for presenting the tone are available: continuous (the tone is ON when the operator touch the button), single pulse (a single pulse with selectable duration is presented when the operator touches the button) or pulsed.

Norm. ON. Selecting the “Normally ON” function for the channel (with the green indicator alight), the relative output will be permanently active, unless the channel is switched off by touching the interrupter. Activating the “Normally ON” function, accordingly, the operating logic of the interrupter is inverted.

Knob. A knob associated with each channel is used by the operator to attenuate the output. In practice, these knobs are used in certain situations for other purposes; for example, with the Settings menu activated, the various settings of the instrument are selected with the two knobs. When the knobs are used to perform a specific function other than that of attenuating the channel output, the sector-shaped indicator adjacent to the knob will light up.

CONTROLS COMMON TO BOTH CHANNELS

At the top of the keyboard there are four buttons, illustrated below, controlling respective functions common to both channels.



Step dB. The first button is used to select the incremental step for the attenuators, which can be 1 or 5 dB.

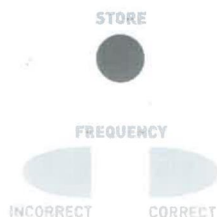
Pulsed. Allows the selection of pulsed mode for presentation of the stimulus signal. The pulse rate — 0.5 Hz, 1 Hz, 2 Hz or custom rate — can be selected touching the screen on the appropriate area. To change the customisable rate, see CHAPTER 11: Settings.

Tracking. When the tracking option is selected, the difference between the intensity of the stimulus and masking signals is maintained constant with any variation in the intensity of the stimulus signal.

Lock. When the lock option is selected, the masking tone will be switched on and switched off together with the stimulus tone. With lock enabled, the interrupter and the Normally ON button of channel 2 are deactivated.

FREQUENCY CHANGE AND STORE

The lower part of the audiometer keyboard includes two frequency change buttons and the *Store* button, which are illustrated below.



Frequency. The two frequency buttons are used to change to the previous frequency and the next frequency. In the case of speech audiometry, these two buttons are used to count the words recognized and not recognized by the patient.

Store. Store is pressed to memorize the threshold at each frequency, in pure-tone audiometry, and the values measured in all other tests. In pure-tone audiometry, furthermore, the instrument can be set so that the test moves on to the next frequency automatically, whenever the threshold is saved. For details on configuration of the automatic frequency change, see CHAPTER 11: *Settings*.

FUNCTION BUTTONS

The top part of the keyboard of Piano audiometer has six dedicated function buttons, illustrated below.



Back. This is pressed to go back to the previous window. For example, if Back is pressed during a pure-tone audiometry test, the main menu will reappear.

New Patient. Pressing the New Patient key will cancel all examinations conducted in the current session.

Print. If the audiometer is equipped with the thermal printer, this button initiates the printout of the current test.

Erase data. Cancels the current data. In pure-tone mode, for example, this clears the symbol on the audiogram corresponding to the selected side (L/R), transducer and frequency.

To Pc. Sends the current examination to a computer, on which Maestro software must be installed (refer to *Maestro – Impedance-Audiometry functionalities – User manual* for more details).

Help. This button opens a context-sensitive help window, i.e. displaying information pertinent to the type of test being conducted. Pressing Help once, this window will open.

Press the button for which
help is required or press the
"HELP" button for information
on the current window

At this point:

- pressing Help a second time, the display shows general information on the functions of the current window;
- pressing any other button, the display will show information relating specifically to that button.

PATIENT-OPERATOR COMMUNICATION

The functions governing communication between the patient and the operator are Talk over, Talk back and the Response LED.



Talk over. This enables the operator to talk to the patient, who will hear the operator's voice by way of the transducer currently selected. Communication is enabled by pressing and holding the button, and disabled on release.

Piano audiometers have a microphone built into the chassis, which can be used to communicate with the patient. If an external microphone is plugged

into the Talk over socket on the rear panel, the built-in microphone will be disabled.

Pressing and holding the Talk over button, the operator can control the communication volume by turning the Channel 1 knob.

If the MIC input is selected during speech audiometry so that the test can be conducted using the operator's own voice, the Talk over function is automatically directed through the same input. The operator will use the same external microphone (connected to the MIC or TALK-OVER input on the rear panel) both to communicate with the patient and to perform live speech exam.

Only for Piano Plus VRA models, if the assistant monitor is enabled (see *CHAPTER 11: Settings*), the TALK OVER function allows the operator-assistant communication: the patient, under these conditions, doesn't hear the operator's voice.

Talk back. This function enables the patient to communicate with the operator. Unlike Talk over, Talk back remains enabled even after the control has been released; to deactivate the function, the operator must press the button a second time.

The voice of the patient can be heard:

- 1) through the speaker incorporated into the chassis;
- 2) through headphones or external speakers connected to the "Monitor" socket on the rear panel, which when plugged in will disable the internal speaker.

For information on adjustment of the Talkback volume, see the section on "Volume Control".

Response. The Response Led, located in the middle of the keyboard, will light up whenever the patient presses the response button. If the patient has two response buttons, you have to see the indication on the display to determine, which button he is pressing.

GAIN CONTROL AND PLAYBACK OF WORD LISTS

Grouped together at the top right of the Piano keyboard are three buttons controlling gain of external inputs, communications between patient and operator, and the operator's monitor output, as illustrated below.



Talk. Pressing the Talk button, the display will show a volume control window for communications between patient and operator. The left hand knob controls the volume of communication from operator to patient, and the right hand knob, of communication from patient to operator. To quit the window, press Talk a second time, or press “Back” function button. The volume settings are retained even after the instrument has been switched off.

Gain. Pressing the Gain button, which is active only when conducting speech audiometry, the display will show a gain control window for the speech material. Gain — controlled using the two knobs — determines the level of the input signal currently selected, or the external input (EXT1 or EXT2), or the internal flash memory, or the microphone (MIC). Gain values for each input are saved internally of the audiometer, and remain stored even after the instrument has been switched off. See *CHAPTER 6: Speech audiometry* for a detailed description of the gain setting procedure.

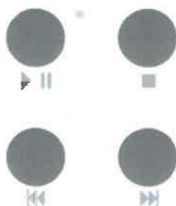
Monitor. Pressing the Monitor button, the display will show a volume control window for monitor signals used by the operator. Control is by way of the two knobs, each serving one respective channel. To switch off the monitor on either channel, simply turn the knob anti-clockwise right down to zero volume. The monitor signal can be heard either on the internal speaker of the instrument, or on headphones or external speakers connected to the Monitor socket on the rear panel. The level of the monitor signal set is saved internally of the instrument and remains stored even after the power has been switched off. If the user enables the “turn off monitor after speech” option (see *Chapter 11: Settings*), the level of the monitor signal is set to its minimum, hence is turned-off, for all the examinations that are not speech-like tests.

Piano Plus VRA models also allow a second operator, e.g. the assistant, to hear the stimulus sent to the patient, connecting the monitor’s headphones at the relative socket on the rear panel. If this feature is enabled (see *CHAPTER 11: Settings*), the monitor volume control window provides the MONITOR AUX / MONITOR function button, that switches between monitor and assistant monitor volume adjustments. As the operator’s monitor signal, control is by way of the two knobs, each serving one respective channel. To

switch off the assistant monitor on either channel, simply turn the knob anti-clockwise right down to zero volume.

Piano is equipped with an internal flash memory of 2 GB capacity, where the operator can store lists of words in .wav format for speech audiometry (see *CHAPTER 11: Customizing the word lists*, for a description of the uploading procedure); accordingly, tests can be conducted without the need for an external CD or cassette tape drive.

The top left of the keyboard presents four buttons, illustrated below, which are used to manage the playback of word lists stored in the flash memory. The buttons are enabled in speech audiometry mode only, when internal material (INT1 or INT2) is selected as the input signal.



Play / Pause. This button is pressed to start playing the current list (indicated in the display), or to pause the list if already playing. The Led remains permanently alight during Play, and blinks as long as Pause is selected. For a detailed description of how word lists are organized in the internal memory, see the final section of *CHAPTER 6: Speech audiometry*.

Stop. Terminates playback of the current list.

Previous. If there is no audio material being played currently, pressing the Previous button will bring up the list preceding the current list. If there is a list playing when the Previous button is pressed, the playback will jump back to the previous word, if the list is indexed, or by 5 seconds if not indexed.

Next. If there is no audio material being played currently, pressing the Next button will bring up the list that follows the current list. If there is a list playing when the Next button is pressed, the playback will jump forward to the next word, if the list is indexed, or by 5 seconds if not indexed.

CHAPTER 5:

Pure tone audiometry

Pure tone audiometry is the standard hearing test used in audiology clinical practice, providing the basis for patient diagnosis and management.

This chapter describes the procedure for conducting pure tone audiometry tests with Piano audiometer.

HEARING THRESHOLD

The *hearing threshold* is a basic concept in the field of audiology. Related to a stimulus, the hearing threshold is the minimum intensity that will elicit an auditory response.

In clinical hearing assessment, more exactly, this is referred to as the *audiometric threshold*, that is, the weakest level of a stimulus signal that the patient is able to hear at least 50% of the time.

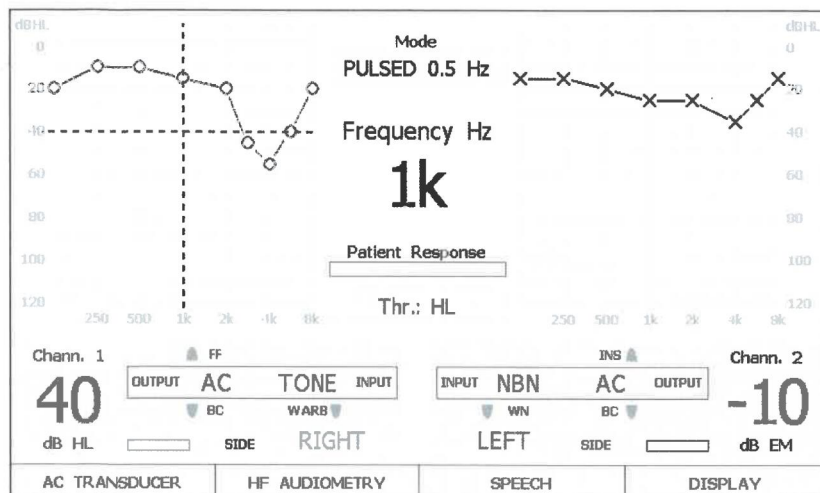
In practice, pure tone audiometry is the test that determines the audiometric threshold of the patient at different frequencies.

The tone signals generated by the audiometer, and the level of the audiometric threshold, are measured in decibels (dB). In reality, the unit of measure is the dB HL (Hearing Level); in contrast to the dB SPL (Sound Pressure Level), which represents the actual intensity of the sound, the dB HL includes a compensating factor whereby a person with normal hearing tested under ideal conditions will have a hearing threshold of 0 dB HL at every frequency. These compensating factors, which are different for each frequency and each type of transducer, have been calculated from studies conducted on a large number of patients and are published in international standards (EN ISO 389-1, 389-2, 389-3, 389-4, 389-5 and 389-7).

PURE TONE AUDIOMETRY WINDOW

To conduct a pure-tone audiometry test, the operator must first bring up the relative window from the main menu (the instrument can be set up in such a way that the pure-tone audiometry window appears automatically after switching on: see *CHAPTER 11: Settings*).

Once accessed, the window in question will look like in the following image.



In the upper part of the display you can find the audiograms. The horizontal and vertical dotted lines on the audiogram indicate the frequency and sound intensity values currently selected for channel 1. The grey area in the lower part of the audiogram indicates the frequency and intensity values that cannot be covered with the selected transducer.

There are two possible viewing modes:

- separated audiograms: left and right ear are on separated audiograms;
- single audiogram: both ears are on the same audiogram.

To toggle between the viewing modes, press the "Display" button on the screen.

The lower part of the screen shows the information, on a grey background, relating respectively to channel 1 and to channel 2, namely:

- level of intensity;
- status of channel (active or inactive);
- input signal (INPUT);
- transducer (OUTPUT);
- stimulation side.

Also displayed, in the central part of the screen, are:

- stimulation frequency;
- presentation mode (continuous or pulsed, with or without the pulse frequency);

- type of threshold selected (HL or UCL, available only in the case of air conduction);
- status of patient response button (or buttons in case the audiometer is equipped with left and right response buttons).

From the pure tone window, you may directly change the transducer used for air conduction tests by pressing the AC TRANSDUCER function button, which is active only when one of the current outputs is the air conduction. Note that it is also possible to select the air conduction transducer in the settings menu (see *Chapter 11: Settings*).

PRESENTING THE TONES AND SAVING THE REPLY

Before commencing a pure tone audiometry test, the stimulation parameters must be set, and in particular:

- 1) the input signal on channel 1 (stimulus): tone or warble;
- 2) the input signal on channel 2 (masking): NBN or WN;
- 3) the transducer for channel 1: headphone (AC), bone vibrator (BC) or speakers (FF);
- 4) the transducer that delivers the masking signal: headphone (AC), bone vibrator (BC), speakers (FF) or insert earphone (INS);
- 5) the method of presenting the stimulus — continuous or pulsed (PULSED button); in the case of pulsed mode, the pulse frequency can be selected touching the relative button on the screen;
- 6) the side to which the stimulus is presented: right (R), left (L) or bilateral (BIL, not available if the output is BC);
- 7) the side on which the masking signal is generated, which is set automatically as the side opposite to that of the stimulus, but can also be set as ipsilateral;
- 8) the intensity and the frequency of the stimulus and of the masking signal.

Once these parameters have been set, the signal can be presented by touching the INTERRUPTER button for channel 1, or the NORM.ON can be pressed to keep the signal constantly active (in this instance, touching the INTERRUPTER button will have the effect of discontinuing the signal)

The same principle applies for activation of the masking signal on channel 2. For a description of the TRACKING and LOCK functions on the masking channel, see *CHAPTER 4: Controls on Piano audiometer*.

Remember that for safety reasons, if the intention is to present a stimulus signal stronger than 100 dB HL, the operator must first press the “Higher dB”

button, which is active only when the intensity of the stimulus reaches 100 dB HL.

Having identified the audiometric threshold of the current frequency, it can be saved by pressing the STORE button and a symbol will appear on the audiogram, corresponding to the signal presented at the frequency and intensity currently selected (see Appendix C for a list of the symbols utilized). If, at a given frequency, the tone presented is not heard by the patient even at the maximum available intensity, the signal can be marked as “not heard” by pressing the “No response” button, which will be active only when the intensity of the signal is at its maximum value.

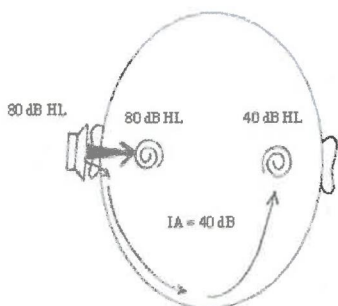
Should an error occur when saving a threshold, the operator can press the STORE button a second time, at the correct intensity — which will have the effect of repositioning the threshold at the new value — or delete the threshold value using the ERASE DATA button.

MASKING

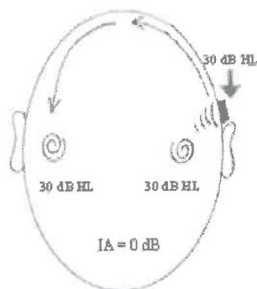
When a signal is presented to one ear, the cochlea of the other ear can also be stimulated, in dissimilar measure, as a result of the sound being transmitted through the bones of the skull. The mechanism whereby a signal presented to one ear stimulates the cochlea of the opposite ear is known as *cross-hearing*. In situations where cross-hearing could occur, a masking signal must be used. Masking consists in raising the threshold of the contralateral ear by presenting an appropriate masking signal (generally a narrow band noise, NBN, centred on the current stimulation frequency) at a predetermined level. This prevents the contralateral ear from sensing the stimulus presented to the ear being tested, which could lead to the responses of the patient registering false positives and affecting the measured threshold.

The unit of measure for narrow band masking noise (NBN) is dB EM (*Effective Masking*). In contrast to dB HL, the correction factor introduced into dB EM is such that when using a given stimulation frequency (e.g. 1 kHz), a narrow band noise of predetermined intensity (e.g. 20 dB EM) will render inaudible any signal of intensity less than or equal to the noise in question (or in the case of the example, any tone of 1 kHz frequency generated at an intensity of up to 20 dB HL).

A fundamental concept applied in the selection of a suitable masking strategy is that of *interaural attenuation* (IA): the reduction of energy in a sound signal presented to one ear and transmitted by bone conduction to the contralateral ear.



Interaural attenuation with AC



Interaural attenuation with BC

For air-conducted signals, the level of IA varies according to the frequency and the transducer adopted (supra-aural headphones or insert earphones) and, to an extent, from one individual to another.

In the case of headphones, reference can be made to the following table, taken from Goldstein BA, Newmann CW (1994) "Clinical masking: a decision making process", in the Handbook of Clinical Audiology by J Katz (ed).

Frequency (Hz)	125	250	500	1000	2000	4000	8000
IA (dB)	35	40	40	40	45	50	50

In the case of insert type earphones (EARTone models 3 and 5), IA is much higher (above 70 dB).

For bone-conducted signals, conversely, IA is near to 0 dB: consequently, one can never be certain which cochlea has been stimulated by a BC tone, irrespective of where the vibrator is positioned, which means that cross-hearing can always be a factor in bone conduction.

Having introduced the concept of interaural attenuation, instances of cross-hearing can be identified with the following formula, in which case a masking signal becomes necessary:

$$AC_{TE} - IA \geq BC_{NTE}$$

where: AC_{TE} = the air conduction threshold for the Test Ear

IA = interaural attenuation

BC_{NTE} = bone conduction threshold for the Non-Test (contralateral) Ear

In the same way as for a test tone, if the masking noise is of sufficiently powerful intensity, it can be transmitted by bone conduction to the test ear. If the intensity of the masking noise is sufficient to mask not only the non-tested

ear but the test ear as well, the effect is referred to as *overmasking*. The maximum intensity of masking noise above which overmasking occurs ($M_{\max}$) is given by this formula:

$$M_{\max} = IA + BC_{TE}$$

Accordingly, overmasking occurs when the level of the masking signal (EML_{NTE}) is as determined by this formula:

$$EML_{NTE} \geq IA + BC_{TE} + 5$$

The masking signal can be delivered through the same headphones as used for the test, or alternatively, the IME-100 insert earphone, which is supplied as an optional accessory with Piano audiometer. This type of transducer has a much higher IA than that of supra-aural headphones (from 70 to 100 dB), which helps to reduce cases of overmasking.

AIR CONDUCTION AUDIOMETRY

The general rule when performing an audiometric test with air-conducted signals is to use a pure tone input, which can be either continuous or pulsed. Referring to the considerations of the previous section, the operator must decide whether or not a masking signal is needed, and determine its level. To ensure a dependable outcome, the test should be conducted in suitably quiet surroundings, and preferably in a soundproof booth. If there is no such enclosure available, the use of special sound-isolating headphones is recommended, in particular Audiocups, which can be supplied as an optional accessory with Piano audiometer. Standard EN ISO 8253-1 specifies the maximum permissible ambient noise level compatible with dependable results.

Having invited the patient to put on the headphones, conduct the test in accordance with the following procedure — taken from EN ISO 8253-1.

Instructions to the patient

Tell the patient to press the button (or raise a hand) when a sound is heard, and release the button (or lower the hand) only when the sound is no longer heard.

Presentation and interruption of test tones

The test tone should be presented for a duration of 1 or 2 seconds. When there is a response from the patient, the interval between successive test tones must

be varied, although never reduced to a duration less than that of the actual tone.

Initial familiarization

Before determining the hearing threshold, the patient must be familiarized with the task by presenting a signal of intensity sufficient to elicit a precise response. After this familiarization step, the operator can be confident that the patient understands the procedure and is able to respond correctly.

The following method of familiarization can be used:

- 1) present a 1000 Hz tone at a clearly perceptible level, say, 40 dB HL for a person with normal hearing;
- 2) reduce the level of the tone by steps of 20 dB until there is no longer any response;
- 3) increase the level of the tone by steps of 10 dB until a response is elicited;
- 4) present the tone again at the same level.

If the responses are consistent with the presentation of the tones, the familiarization process is complete. If not, the procedure should be repeated. Following a second failure, repeat the instructions.

In cases of profound deafness, these procedures may not be applicable.

Estimation of hearing threshold (ascending method)

Conduct the test initially on the ear that the patient considers to be the better ear. The different frequencies should be tested in the following sequence: 1000, 2000, 4000, 8000, 500, 250 Hz, including half octaves if appropriate.

Perform the following sequence of steps.

- 1) Present the first tone of the test at a level 10 dB less than the lowest level of the response given by the patient during the familiarization session. Following each tone that fails to elicit a response, increase the level of the test tone by steps of 5 dB until a response is forthcoming.
- 2) Following the response, reduce the level by degrees of 10 dB until there is no response, then begin the ascending sequence again. Continue until the patient produces three responses at the same level on a maximum of five ascending sequences.

Using the ascending method, if less than three responses at the same level are elicited on five ascending sequences (or less than two responses on three ascending sequences, using the short method), present a tone at a level 10 dB higher than the level of the last response. Repeat the test procedure.

It has been shown that a shortened version of the ascending method gives comparable results, and in certain instances can be considered suitable

for the purpose in question. Using the short method, continue with the test until the patient gives at least two responses at the same level on a set of three ascending sequences.

- 3) Move on to the next frequency, starting at a level that ought to be audible on the basis of the previous responses, and repeat step 2). Complete the test on one ear, at all the frequencies, in the sequence indicated. Repeat the measurement at 1000 Hz. If the results of the repeat test at 1000 Hz on the same ear are comparable with the first, registering a difference of less than 5 dB from the previous level, then proceed with the other ear. If there is an improvement of the order of 10 dB in liminal hearing, repeat the test at other frequencies in the same order until the values reflect a deviation equal to or less than 5 dB.
- 4) Continue until the test has been completed on both ears.

BONE CONDUCTION AUDIOMETRY

Given that bone-conduction IA is near to 0 dB, the exact determination of the hearing threshold for an ear using bone-conduction audiometry requires masking of the non-test contralateral ear at all levels.

Follow the steps indicated below to establish the threshold level.

- 1) Position the bone vibrator on the patient's mastoid, behind and as near as possible to the conch, without touching, and place the masking headphone over the non-test ear (the unused headphone should be positioned forward of the test ear, leaving the cavity exposed). Make certain that the head bands of the two transducers do not interfere with one another.
- 2) Begin the test with the ear the patient considers to be the better ear, at a frequency of 1000 Hz.
- 3) Establish the threshold level without the masking signal, using the shortened ascending method described in the previous section. Bear in mind that the result of this operation cannot serve as a true estimate of the bone-conduction threshold, given the possibility that the non-test ear could be affected by occlusion (see next section).
- 4) Activate the masking noise and establish the correct intensity of the masking component — hence the hearing threshold — using the Plateau method described in the next section.

- 5) Move on to the other frequencies, following the same sequence as indicated for air-conduction testing. Continue until the test has been completed on both ears.

HOW MASKING IS APPLIED

As mentioned previously, whenever cross-hearing could be an issue, a masking noise must be applied to the non-test ear, delivered by way of the headphones or a dedicated insert earphone.

The method described here for determining the level of the masking tone is the so-called 'plateau' technique described by J.D. Hood in 1960. This involves gradually increasing the masking noise applied to the non-test ear in such a way as to arrive at a plateau — that is to say, a range of masking values across which there is no increase in the hearing threshold of the test ear. The presence of the plateau suggests that, within the range of masking intensity values in question, there is no undermasking (i.e. a level not sufficient to prevent cross-hearing) and no overmasking.

The plateau technique involves the following three steps.

- 1) Find the threshold for the ear being tested, without masking.
- 2) Activate the masking noise at an initial level of 10 dB higher than the air conduction threshold for the non-tested ear (in the case of bone conduction, see the following note); except in certain particular cases, this level will not produce overmasking.
- 3) Check the threshold of the test ear again. If the threshold of the test ear has not changed, increase the intensity of the noise by steps of 5 (or 10) dB, checking the value after each increment; if there is no change in the threshold over three successive increases in the intensity of the noise (or two increases, for steps of 10 dB), this means that the plateau has been found, and the value can be considered as the threshold. Conversely, if there is a change in the threshold value, this indicates that it was influenced by undermasking, and the procedure must be repeated with the new threshold level.

If bone-conduction is being used for the test, the initial level of the masking signal should be increased to compensate for the *occlusion effect* (OE). OE — due to the headphone being placed over the non-test ear — causes an increase of the bone-conduction tone threshold in the frequency range between 250 and 1000 Hz; in particular, the threshold in question increases by 15 dB at 250 Hz and 500 Hz, and by 10 dB at 1000 Hz. The initial value

of the masking noise therefore needs to be higher than the AC threshold of the non-tested ear, by 25 dB at 250 Hz and 500 Hz, and by 20 dB at 1000 Hz.

UCL AUDIOMETRY

The UCL (Uncomfortable Level) test is used to determine the sound intensity at which acoustic stimuli become intolerable to the patient. This information is important in establishing the upper limit of the patient's hearing range, typically for the purpose of fitting hearing aids, as well as for detecting instances of recruitment.

To run a UCL test, which is possible only by air conduction, simply press the yellow area on the screen indicating the currently selected threshold.

PURE TONE AUDIOMETRY WITH INDEPENDENT CHANNELS

As a clinical audiometer, Piano allow the user to fully control separately and independently its two channels. Firstly, this option should be enabled from the setup menu, as described in Chapter 11.

If so, press the yellow area where the frequency value is displayed, then it may be possible to set for each channel a frequency value and either pure tone stimuli or masking noises.

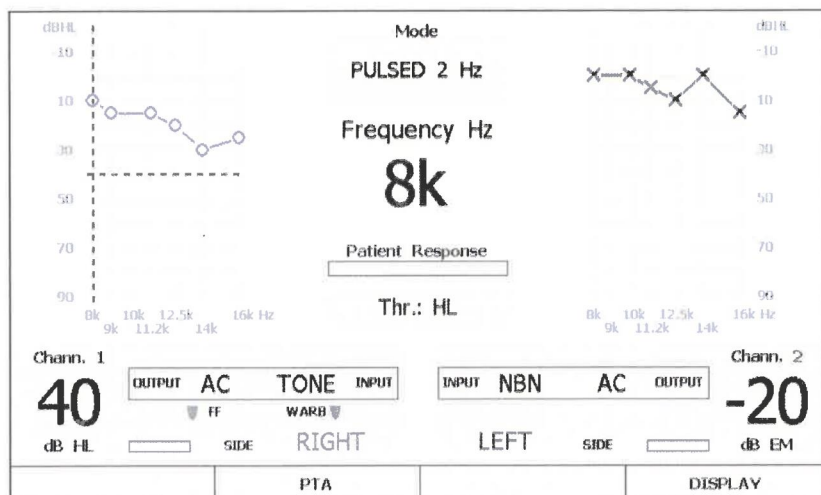
Press again on the frequency value area to switch back to normal channel behavior.

HIGH FREQUENCY AUDIOMETRY (ONLY PIANO PLUS)

The High Frequency audiometry allows to determine the hearing threshold in the range of frequencies between 8 kHz and 20 kHz (16 kHz for Free Field). Determining the thresholds in this range permits to diagnose hearing damages caused by the noise exposure or by therapies with ototoxic drugs. As a matter of fact, these kinds of hypoacusia affect the higher frequencies prior than the lower ones.

The HF test can be conducted by air conduction using the supplied Sennheiser HDA-200 or HDA-300 headphones, or in free field.

The following image represents the HF audiometry window.



The window and all the controls are exactly the same as those of standard frequency audiometry, except for the two audiograms, reporting here the high frequency range.

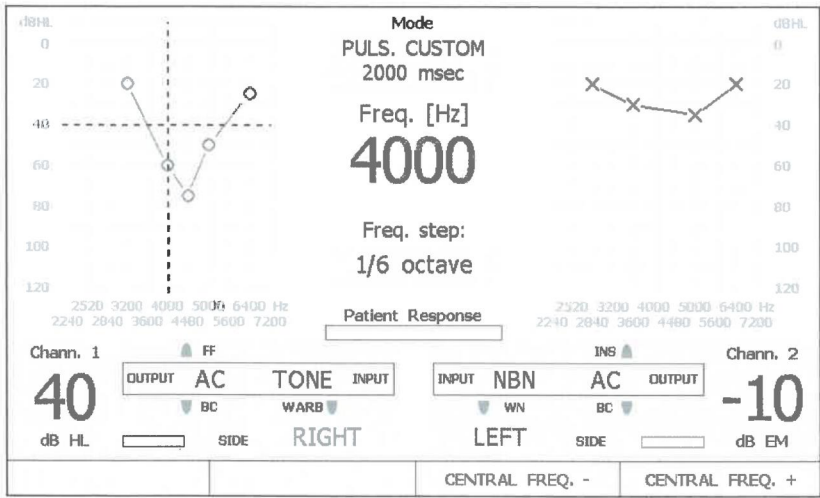
The frequencies 18 and 20 kHz are available only by AC only if enabled in the device settings. The tones at these frequencies do not any normative data, therefore their intensity cannot be expressed in dB HL but in dB SPL. For this reason, these frequencies are even not displayed on the audiogram.

Pushing the PTA function button, it is possible to directly move from HF to standard audiometry (and vice versa), easily allowing an exam over the full range of frequencies. This command is available only if you selected the HDA-200 or HDA-300 headphones as the transducer for AC audiometry, or if the current output is the free field.

MULTIFREQUENCY AUDIOMETRY (ONLY PIANO PLUS)

With the multifrequency audiometry it is possible to determine the patient's hearing threshold with a higher resolution in frequency with respect to the traditional audiometry.

The following image represents the multifrequency audiometry window.



The multifrequency audiometry is basically identical to the traditional audiometry, except for the different frequencies tested; the window and the available controls are therefore very similar to those of the pure tone exam, and we do not need to further describe them.

Piano allows the multifrequency exam around each one of the 11 standard audiometric frequencies; in particular, it is possible to test 5 frequencies lower and 5 higher than the central frequency, with a step selectable between 1/3, 1/6, 1/12 and 1/24 octave.

Using the function buttons CENTRAL FREQ. - and CENTRAL FREQ. + it is possible to change the current central frequency, whereas to modify the frequency step just touch the screen on the relevant yellow area.

CHAPTER 6:

Speech audiometry

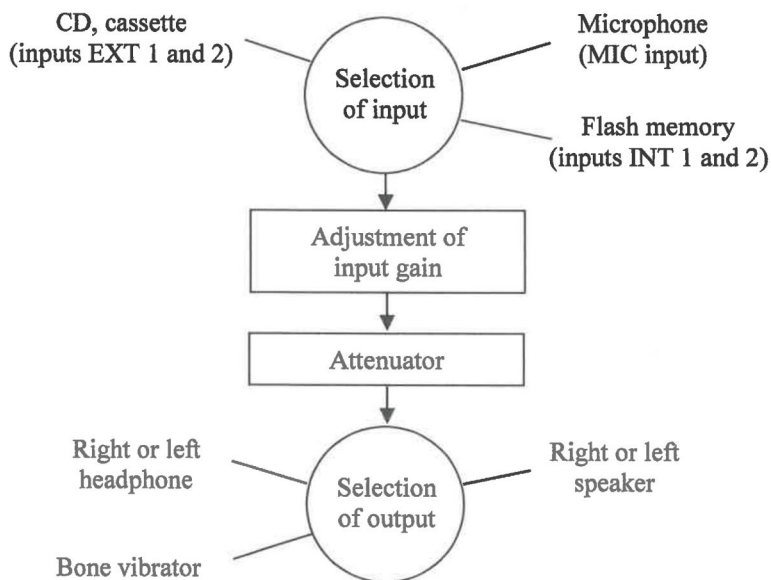
In addition to pure tone audiometry, there are various other tests that can be conducted with the audiometer, of which the most important and widespread is speech audiometry. This chapter explains how to conduct a speech audiometry test using the Inventis Piano audiometer.

SPEECH AUDIOMETRY TEST

Pure tone audiometry provides only partial information on the abilities of the patient to hear and understand the spoken voice, which is the most important of audible signals. To understand how a patient hears the spoken voice, speech stimuli must be utilized, and the testing method is referred to as “speech audiometry”.

In speech audiometry, the patient is presented with a succession of standardized speech stimuli, typically single syllables, words or phrases, designed to assess certain aspects of the patient’s hearing ability. The speech material can be presented directly by the operator, talking into a microphone, or recorded on a CD or a tape cassette and reproduced by a player connected to the EXT inputs of the audiometer, or alternatively, stored in a flash memory with which the instrument is equipped.

The following diagram illustrates how the speech material is presented to the patient from the audiometer.



Selection of input

The input signal for speech audiometry can be the microphone (connected to the MIC or TALK OVER input on the rear panel depending on the setup), an external audio source (CD or cassette player) connected to inputs EXT1 and EXT2 or the internal flash memory (INT1 and INT2), on which the speech material is already stored.

The signal is selected by pressing the INPUT button on the audiometer.

Adjustment of input gain

Before starting a speech audiometry test, the level of gain on the selected input must be adjusted. The purpose of this operation is to ensure that recorded speech material utilized for the test (or the operator voice in case of live speech test) will be played back at the correct volume. In case of recorded speech material, the input gain will be correct if, playing the calibration tone supplied with the speech material, the loudness measured on the VU-meters of the two channels — displayed on the Piano screen — touches 0 dB, that is to say, the point at which the meter changes from green to red. In case of live speech test, the gain will be correct if the mean value measured by the VU-meter of channel 1 is 0 dB while you speak test words and the distance between yourself and the microphone is the usual kept during the test.

If the level is incorrect, press the GAIN button and make the necessary adjustment using the two knobs on the audiometer.

The gain level for each input is saved by the instrument and will be set again at the same level even when the instrument is switched off and powered up subsequently.

Attenuator

The speech signal is adjusted to the level set by the operator (level of channel 1).

Selection of output

The speech signal can be presented to the patient through headphones (AC), on loudspeakers (FF), or by way of the bone vibrator (BC). In the first two instances, the operator can select the side to which the stimulus is directed, namely right, left or bilateral (pressing the LEFT and RIGHT buttons simultaneously). To select the output transducer, press the OUTPUT button.

MASKING AND COMPETING SIGNAL

As in pure tone audiometry, a masking signal can be used in speech audiometry to avoid the eventuality of measurement errors being induced as a result of cross-hearing. The masking signal is generated through channel 2 of the audiometer; the recommended signal for speech audiometry is *speech noise* (SN), which produces an energy output concentrated in the frequency band typical of the human voice. The Piano audiometer also features a white noise (WN) as the masking signal.

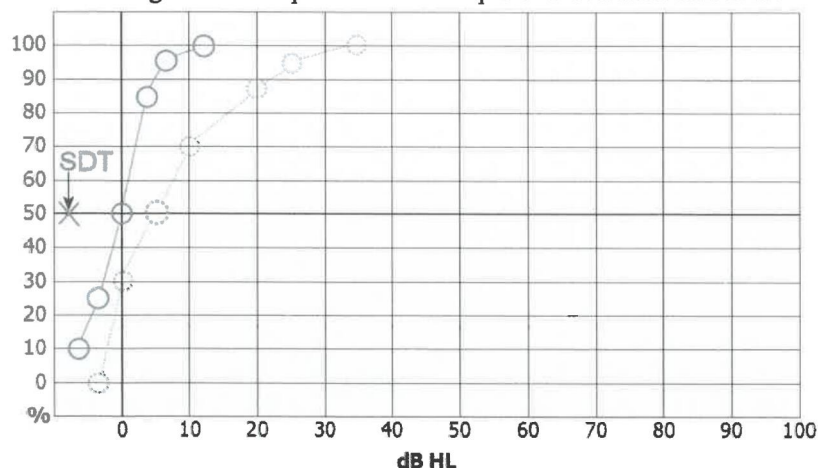
To assess the ability of a patient to recognize speech in an environment with background noise, in other words under conditions typical of everyday life, speech audiometry can be conducted by presenting a *competing sound* either to the tested ear or to the contralateral, non-tested ear. The competing sound, which is generated through channel 2 of the audiometer, can be the speech noise or white noise mentioned above, or a signal incorporated into the audio track of the selected speech material, recorded on the channel opposite to that containing the word lists.

ARTICULATION FUNCTION, SPEECH RECOGNITION AND SPEECH DETECTION THRESHOLDS

The articulation function (or performance-intensity function) is the curve that describes the speech recognition score (average percentage of correct answers) as a function of speech intensity level. The articulation function

provides information on how speech material of different types (monosyllabic words, spondaic words, etc.) is identified correctly by the patient in relation to the intensity of presentation.

The following illustration provides an example of articulation functions.

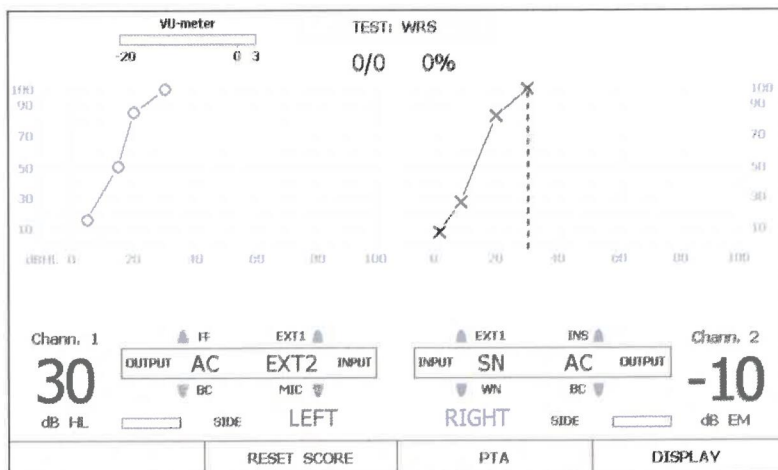


The two curves in the graph relate to two different types of speech material, and more exactly, lists of spondaic words (continuous line) and of monosyllabic, phonetically balanced words (dotted line). The level of intensity at which 50% of correct responses are obtained with lists of spondaic words is known as the *Speech Recognition Threshold* (SRT). The average SRT for adults with normal hearing is 20 dB SPL; standard EN 60645-2 defines this level as equivalent to 0 dB HL. In the case of speech audiometry, accordingly, to convert a value of intensity expressed in dB SPL to the corresponding value in dB HL, simply subtract 20 dB from the value. The articulation function in persons with normal hearing presents a steep curve: on average, 100% of correct responses will be registered at a value as low as 27.5 dB SPL (or 7.5 dB HL).

Also indicated in the foregoing graph is the *Speech Detection Threshold* (SDT), that is, the intensity at which the patient detects the speech signal (without comprehending it) 50% of the times it is presented. The SDT value for a person with normal hearing is around 13 dB SPL (or -7 dB HL).

SPEECH AUDIOMETRY WINDOW

To run a speech audiometry test, the relative window must be opened from the main menu. Once accessed, the window in question will appear as in the following image.



The central part of the display is occupied by the articulation curves of the right and left ears. As in pure tone audiometry, it is possible to display both ears on the same graph rather than on two separated graphs. To toggle between the two viewing mode, press the “Display” button on the bottom of the screen.

The items of information relating to channel 1 and to channel 2, i.e.:

- level of intensity,
- status of channel (active or inactive),
- input signal (INPUT),
- transducer (OUTPUT),
- stimulation side,

are grouped together in an area with a grey background located on the bottom of the screen.

The upper part of the screen shows:

- number of correct and incorrect responses elicited from the patient;
- percentage of correct responses. This value is determined on the basis of the method selected in the settings (see *Chapter 11: Settings*);
- VU-meters relative to the two channels (or channel 1 only, if the channel 2 input is SN or WN);

- the type of test selected (choices are between WRS, SRT, MCL and UCL).

If the input selected for channel 1 is the internal flash memory, the following information will also be displayed below the graphs:

- speech material currently selected;
- number of the current list;
- the last word presented to the patient (only if the material is indexed: see next section);
- symbol indicating the status of the player (play, pause or stop).

The furnished talk over microphone or the optional desktop microphone can be used to perform live speech audiometry, depending on the option selected on the instrument settings at the "Live speech microphone" item (see *CHAPTER 11: Settings*).



The desktop microphone shall be placed at a distance not greater than 15 cm from the mouth to reduce the background noise

The responses given by the patient are saved by pressing the two frequency selection buttons, which are also labelled CORRECT and INCORRECT. The mode in which the responses are saved will depend on the "Speech score mode" option selected in the settings for the instrument (see *CHAPTER 11: Settings*).

Whatever the counting method selected, a correct response is recorded by pressing the CORRECT button. In the event of an incorrect response, press INCORRECT if Mode 1 is selected; if Mode 2 is selected, do not press any button. With Mode 2, in effect, pressing the INCORRECT button will have the effect of reducing the 'correct' count by one; accordingly, this is used only to rectify an error, when an incorrect response has been identified mistakenly as correct.

With Mode 1, the button RESET SCORE is active, which resets the current correct / incorrect answer counters and the percentage.

If the option 'WRS single point' has been enabled from the setting menu, the Word Recognition Score is calculated as a single point instead of using a graph. In this case, when the current outputs are either air conduction or free field, you can select the same input for both channels. Therefore, it is possible to simultaneously send the stimulus to the right and left ear at different levels.

Apart from the WRS speech audiometry type explained above, the Piano also offers the chance to measure single thresholds such as SRT, MCL and UCL.

Those type of measurements may be simply selected by pressing on the touch button indicating the current 'Test type'.

Remember that if the free field equivalent filter for the headphone output has been enabled in the settings, this information will appear in the top part of the window. The purpose of this filter (the pertinent specifications are indicated in reference standards) is to render the results of speech audiometry conducted through headphones as similar as possible to those obtained in free field conditions.

USE OF INTERNAL SPEECH MATERIAL

The Piano audiometer is equipped with a 2 GB flash memory, on which preferred speech material can be stored using the *Audio Tracks Indexing Tool (ATIT)*. The use of ATIT software is fully described in the *ATIT User Manual* located in the *Inventis Software Suite*. The use of material stored in this way has two key advantages:

- 1) CD players or external cassette tape machines can be dispensed with (these tend to be delicate and cumbersome, and are not medical devices);
- 2) if the material is indexed using the ATIT software application, each word will be displayed on the screen as it is presented, and there is no need to activate the monitor signal.

To use material stored in the flash memory, simply select INT1 or INT2 as input on channel 1, and possibly on channel 2 if a competing sound is to be utilized for the test.

The internal flash memory is organized as follows:

- a directory with a set of folders, each one identifying the type of material stored (for example, logotomes, spondees, phrases, etc.);
- each folder contains a set of *wave* files, corresponding to the lists of words of the type identified by the name of the folder; the filename, attributed by the ATIT software, will generally be a label such as "Track 1", "Track 2", etc.

Bear in mind that the organization of the flash memory is entrusted to the user (or the dealer), and implemented by means of the ATIT software; consequently, it could be different to that described above.

Before playing a list from the flash memory, the required material must first be selected by pressing the MATERIAL function button. Pressing the button repeatedly has the effect of scrolling cyclically through the folders. The folder currently selected appears in the display.

Once the material has been selected, the files of the first list in the folder can be played by pressing the relative button — “Play” — located at the top left of the keyboard. For a detailed description of the controls used to play word lists, see *CHAPTER 4: Controls on Piano audiometer*.

Remember that the GAIN levels for internal inputs 1 and 2 (carrying the speech material and the competing sound, respectively) are calibrated in the same way as adopted normally for the external inputs, that is to say presenting a test tone, which in the case of the internal inputs will be a *wave* file stored in the flash memory, pressing the GAIN button and adjusting the levels so that the volume of the sound registering on the two VU-meters is 0 dB. This level is saved by the audiometer, consequently there will be no need to repeat the operation after the instrument has been switched off.

CHAPTER 7:

Supra-threshold, MLD Stenger, MHA and special tests

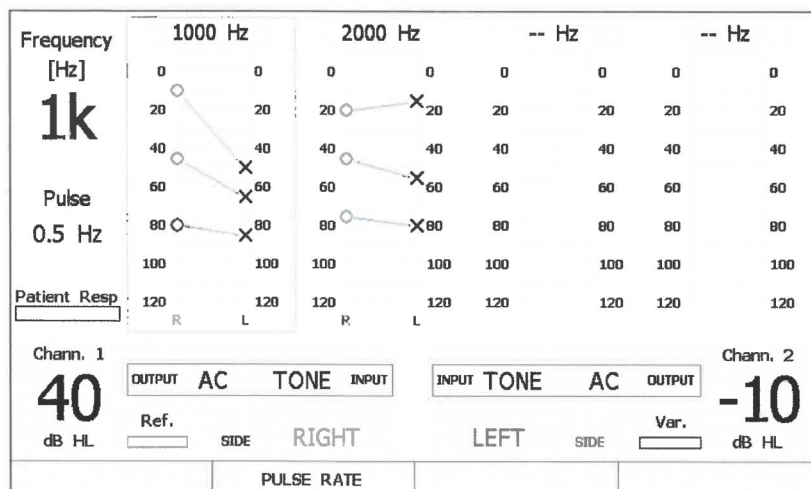
Whilst the measurements obtained with pure-tone and speech audiometry tests can give an indication of conduction, sensory or mixed problems, supraliminal tests allow the audiologist to identify the level of hearing damage in greater detail, and in particular to differentiate between cochlear and retrocochlear disorders. This chapter describes the supraliminal tests that can be conducted with the Piano audiometer, along with three other tests — MLD, Stenger and Master Hearing Aid — likewise available on the Piano model.

ABLB (FOWLER)

The Alternate Binaural Loudness Balance test (ABLB) is a procedure for determining the presence of recruitment. It is applied in cases of unilateral hearing loss or where there is an asymmetry of 25-60 dB between the tone hearing thresholds of the two ears, measured by air conduction at a given frequency.

The ABLB test involves presenting a tone to the two ears alternately, at the same frequency, but at a different intensity. The aim is to present a stimulus to the good ear (the reference ear) at different intensities, and to find the corresponding levels of stimuli presented to the poor ear that are perceived as being of the same loudness. The pairs of values obtained in this way go to make up a "loudness balance graph".

The graphic interface of the ABLB window is illustrated below.



ABLB test window

The channel associated with the good ear is denoted *Ref*, and the channel associated with the poor ear denoted *Var*.

Four graphs are displayed side by side, showing the results of tests conducted under different conditions (frequency of stimulus signal or side).

The active graph (that relating to frequency, on the side currently selected) is highlighted by a green rectangle.

The *PULSE RATE* button serves to set the frequency with which the tone is alternated between the two ears. Permissible values are 0.5 Hz, 1 Hz and 2 Hz.

Once four different tests have been saved, the operator can navigate between those for which the side of the good ear is the same as the side selected currently as the *Ref* channel, using the *Frequency* buttons.

The ABLB test starts generally with the levels of the tone on the two sides equal to the hearing threshold values for the given frequency. The level of intensity is then raised for the good ear by increments of 10 to 30 dB. Following each such increase, the intensity of the signal presented to the poor ear is also raised until the patient experiences a sensation of equal loudness on both sides. Having arrived at the pair of signals perceived by the patient as being the same, the *STORE* button can be pressed to save the combination on the loudness balance graph.

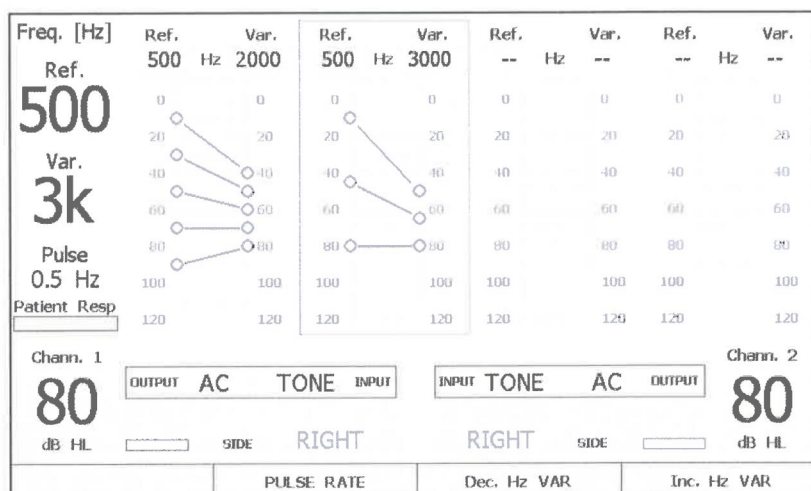
MLB (REGER)

The MLB (Monaural Loudness Balance) test is suggested for patients with binaural hearing loss. It consists in presenting to the same ear two alternate tones, with different frequency and intensity.

Aim of the MLB test is verifying if the difference between the hearing sensitivity of two different frequencies remains unchanged at supra-threshold intensities, or decreases due to the presence of recruitment.

As in the ABLB exam, also in the MLB the goal is finding, for different intensities of the tone delivered at the better frequency (*Reference* frequency), the correspondent values of intensity at the worse frequency (*Variable* frequency) perceived by the patient as with the same level. The pairs of values obtained are plotted on the “intensities balance graph”.

he graphic interface of the MLB window is illustrated below.



MLB test window

The channel associated with the better frequency is the *Reference* (Ref), whereas the other is the *Variable* (Var).

Four graphs are displayed side by side, showing the results of tests conducted under different combinations of frequencies and side.

The active graph (that relating to frequency, on the side currently selected) is highlighted by a green rectangle.

The *PULSE RATE* button serves to set the frequency with which the tone is alternated between the two frequencies. Permissible values are 0.5 Hz, 1 Hz and 2 Hz.

Once four different tests have been saved, the operator can navigate between them using the *Frequency* buttons.

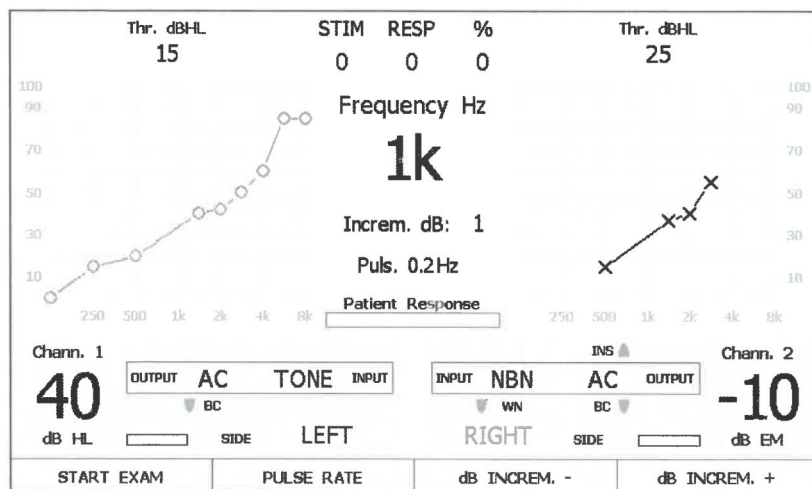
The MLB test starts generally with the levels of the tones equal to the hearing threshold values for the two selected frequency. The level of intensity at the reference frequency is then raised and, after each increment, the intensity of the variable frequency is also raised until the patient experiences a sensation of equal loudness on both frequencies. Having arrived at the pair of signals perceived by the patient as at the same level, the STORE button can be pressed to save the combination on the intensity balance graph.

SISI (JERGER)

The Short Increment Sensitivity Index (SISI) test assesses the ability of the ear to identify brief variations of intensity in a continuous pure tone.

As a rule, the test is conducted by presenting a continuous pure tone at different frequencies, selecting an intensity 20 dB above the hearing threshold identified previously for the ear and at the test frequency, introducing small increments in intensity of short duration and asking the patient to press the button each time an increment is perceived.

The SISI test window is illustrated below.



SISI test window

The areas with the grey background on the bottom of the window show the same items of information, relating to the status of channels 1 and 2, as appear in the pure tone audiometry window.

In the middle of the screen you can find the frequency of the tone and the rate at which the increments are presented. This latter value can be changed by pressing the button PULSE RATE; permissible settings are 0.2 Hz, 0.5 Hz and Random (between 0.2 Hz and 0.5 Hz, changing at each increment).

The upper half of the window displays information on the progress of the test. Indicated on the top line are the number of increments presented (*STIM*), the number of responses made by the patient to the stimuli (*RESP*), and the percentage of responses to the total number of stimuli generated (%). Also indicated are the levels of the PTA threshold for the type of output currently selected.

The central part of the screen is occupied by the left and right SISI graphs: these show the percentage of increments perceived by the patient for each frequency analysed.

The amplitude of the increments can be set, using the dB INCREMENT- and dB INCREMENT+ function buttons, to either, 0.4, 0.6, 0.8, 1, 1.5, 2, 3, 4 and 5 dB; increments of 5 dB should be used only for the initial familiarization stage of the test, during which the responses made by the patient to the stimuli will not be counted.

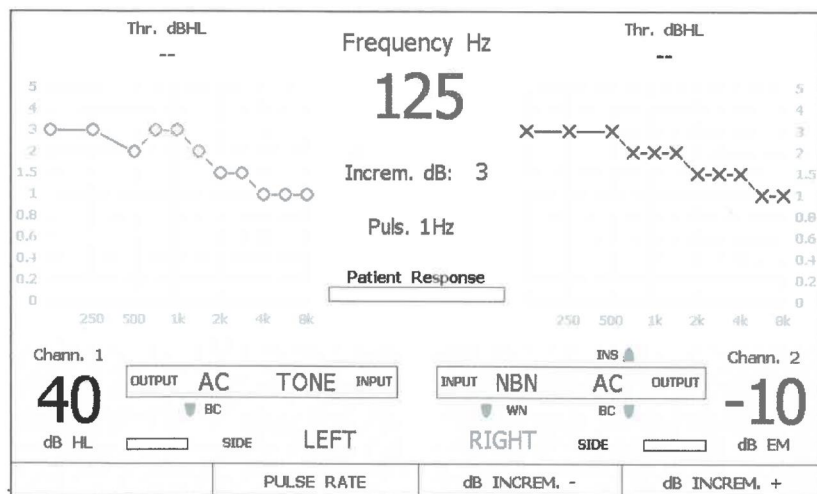
The SISI test is an automatic procedure. Once the frequency and the intensity of the tone have been set, the procedure is set in motion by pressing the button START EXAM. A sequence of 20 increments will be presented to the patient, during which the responses are counted only if the button is pressed within one second of the increment being generated. The analysis of the selected frequency ends automatically once the 20 increments have been presented; the sequence can however be aborted by pressing the END EXAM button (which replaces the START EXAM button once the test is in progress).

Increments of 1 dB should be imperceptible, or no more than barely perceptible, to patients with normal hearing or with transmission or retro cochlear hearing loss; accordingly, if the percentage of increments perceived by the patient is higher than 30%, this could be an indication of cochlear disorder.

DLI (LÜSCHER)

The Difference Limen for Intensity (DLI) test is very similar to the SISI; the purpose of the DLI test is to evaluate the amplitude of the smallest variation

in intensity of a pure tone that can be perceived by a patient. In effect, there would appear to be a connection between recruitment and the ability to distinguish increments of less than 1.5 dB HL. The DLI test window is illustrated below.



DLI test window

The area on the bottom of the display shows the same information as for the SISI test.

In this instance the middle part shows the current frequency, the amplitude of the increments currently selected and their repetition rate; above the graphs, you will find the PTA thresholds measured previously at the current frequency for the selected transducer.

The two DLI graphs show the minimum amplitude of the increment perceived by the patient at the indicated stimulus frequency, for the left and right ear.

The test involves presenting a pure tone to the patient, at an intensity around 40 dB higher than the measured audiometric threshold, introducing increments of a given intensity at regular intervals (0.5 Hz, 1 Hz or 2 Hz), selected with the button PULSE RATE. The value of the increments is then set to 0 dB, and gradually raised (button dB INCREM +), asking the patient to indicate when the continuous tone seems to change to a pulsed tone. Once the level has been identified, it is saved on the graph by pressing STORE.

Possible increments are: 0, 0.2, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, 1, 1.5, 2, 3, and 5 dB.

MLD (ONLY PIANO PLUS)

The Masking Level Difference (MLD) test is useful for the diagnosis of Central Nervous System impairments; in particular, it allows to measure the function of the lower brainstem, i.e. where the signals from the two ears are compared.

The exam consists in presenting to both ears a tone (usually interrupted and with frequency of 500 Hz) and a noise of fixed intensity (normally 60 dB EM). Aim of the test is finding the minimum intensity of the tone heard by the patient in the three following conditions:

- 1) S(0) N(0): both stimulus and noise are in phase: the signals presented to both ear are therefore identical under this condition;
- 2) S(180) N(0): stimulus out-of-phase (i.e., the phase of the tone presented to the left ear is opposite as that to the right ear), noise in phase;
- 3) S(0) N(180): stimulus in phase, noise out-of-phase.

The threshold of the tones determined in the presence of noise for each one of the three hearing conditions is determined using the Békésy tracking procedure; the threshold is usually lower in out-of-phase conditions than in in-phase.

The MLD is defined as the difference in threshold between the in-phase and the out-of-phase (usually S(180) N(0)) conditions. For a 500 Hz tone, the MLD should be greater than 7 dB and is usually around 12 dB.

The MLD test window is illustrated below.

Figure 1 displays a simulated audiometer interface. The screen shows various settings and a frequency scale. The top left section indicates the frequency in Hz, with a large '1000' and a scale from -10 to 120. The top right section shows 'MLD Mode' with 'S(0) N(0)' and 'dB/sec' with '5'. The middle left section shows 'Mode' with 'CONT.' and 'Patient Response' with a bar graph. The middle right section shows 'Time/Mode' with '30 s'. The bottom left section shows 'Chann. 1' with '40' and 'dB HL' and a control panel with 'INPUT', 'AC', 'TONE', and 'INPUT'. The bottom right section shows 'Chann. 2' with '-10' and 'dB EM' and a control panel with 'INPUT', 'NBN', 'AC', and 'OUTPUT'. The center features a large 'BILATERAL' text with a small 'WN' icon above it. The bottom has a 'START EXAM' button.

MLD test window

As in the other tests, the lower portion is occupied by the information about the status of channel 1 and 2.

In the central part of the display you will find the graph of the exam. The x axis is divided in four parts, each of which related to a particular condition of tone and noise (note that $S(0) N(0)$ is tested twice); the y axis is instead the intensity of the tone presented to the patient.

The left portion of the display shows the frequency of the stimulus and the presentation mode, which can be either continuous or interrupted (suggested) with a frequency of 2.5 Hz.

In the right portion of the display you will find the exam parameters, i.e.:

- the current presentation mode for tone and noise;
- the rate at which the intensity of the tone changes (1, 2.5 or 5 dB / sec);
- the duration of the exam for each presentation mode.

To change the values of these parameters, just touch the relevant area of the display.

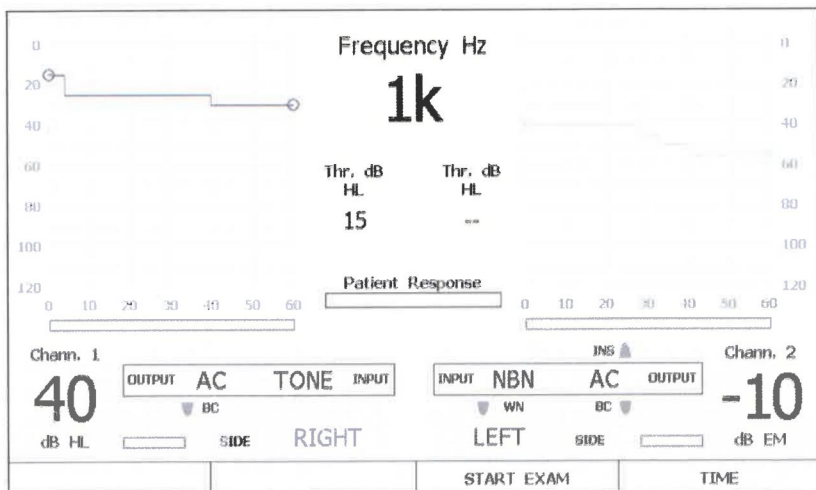
The MLD in Piano is an automatic test; during the examination, the following conditions are tested: $S(0) N(0)$, $S(180) N(0)$, $S(0) N(180)$ and again $S(0) N(0)$. The intensity of the tone presented to the patient is controlled through the response trigger: he has to keep it pressed until he can hear the tone (the intensity will decrease), and release it as soon as he cannot (the intensity will increase).

As in the other automated tests, to start it you need to press the START function button, whereas, if you want to stop it before it ends, push STOP function button.

TONE DECAY

This is a monaural test that can reveal instances of pathological adaptation and fatigue, in other words, loss of hearing sensitivity associated with continuous acoustic stimulation.

The Tone Decay test window is illustrated below.



Tone Decay test window

As in the case of the tests described previously, the bottom portion of the window show the status of channels 1 and 2; displayed in the center, between the graphs, are the current frequency and the tone thresholds (for right and left ear) identified previously for the frequency currently selected. This information is useful in determining the intensity at which to conduct the test. The central part of the screen is occupied by the tone decay graphs for the right and left ear: the 'x' axis indicates the time, in seconds, whilst the 'y' axis indicates the level of the tone presented to the patient. The graph can show up to 4 traces — relative to the stimulation side currently selected — each relating to a specific stimulation frequency. The trace for the current frequency is brought to the front (displayed in a stronger colour). Located below each graph is a progress bar showing the total time, and the time elapsed since the start of the test.

The test consists in presenting a continuous stimulating tone to the patient, generally by air conduction, at a given frequency and at an intensity equal to the hearing threshold for that frequency; the patient is required to press and hold the button for as long as the signal can be heard, and release when the signal can no longer be heard. At this point, the operator increases the intensity of the sound by 5 dB and the test proceeds.

The test can last for 60 or 120 seconds, the duration being selected with the button DURATION.

The test is started by pressing START EXAM button, and can be stopped at any time before the set time elapses by way of the END EXAM button (which replaces START EXAM once the test is in progress)

As mentioned previously, the graph can contain up to four traces; once the test has been run on four frequencies, the START function will be disabled and no further traces can be added unless one of the existing four is first removed by pressing the ERASE DATA button.

The difference between the initial intensity of the stimulus and the intensity at the end of the test reflects the degree of *adaptation*. Adaptation values of 5 – 10 dB for a test of 60 seconds duration are considered physiological.

STENGER

The Stenger test can be used to establish whether or not a measured hearing threshold is genuine. It is based on the 'Stenger effect': if a sound is presented to both ears of an individual at a single frequency, but simultaneously at different intensities, it will be heard only by the ear exposed to the higher intensity.

Having established the hearing threshold for a given frequency, the tone is presented to the good ear at a level 5-10 dB higher than the threshold, and presented to the bad ear at a level slightly lower than the supposed threshold. If there is a genuine loss of hearing in the bad ear, the individual will indicate that the sound can be heard in the good ear. A different response means that the hearing loss is not genuine.

The Stenger test can be conducted using pure tone signals or speech material. The Stenger test window is illustrated below.

Mode CONTINUOUS									
Thr. dBHL		Frequency Hz				Thr. dBHL			
--		1k				--			
Patient Response 									
Chann. 1		MIC				Chann. 2			
40	OUTPUT	AC	TONE	INPUT	INPUT	TONE	AC	OUTPUT	45
dB HL			WARB					dB HL	
SIDE	RIGHT		LEFT		SIDE				

Stenger test window

Selecting a pure tone or warble input, the central area of the display will show the stimulation frequency and the thresholds established previously in the course of pure tone audiometry tests conducted on the right ear and the left ear.

If on the other hand the test is conducted using speech material, selecting the EXT, INT or MIC as the input, the central area of the display will show the VU-meter and, in the case of the INT input, the selected speech material and list.

No results are saved for this type of test. Consequently, there is no function allowing reports to be printed or sent to a computer.

MASTER HEARING AID

The Master Hearing Aid (MHA) test can be used to assist the selection of a hearing aid for patients with impaired hearing. With the MHA test, the audiometer can simulate the use of a hearing aid by filtering the speech signal sent to the patient; in this way it is possible to verify and quantify any improvement in speech recognition attributable to the introduction of a hearing aid.

Various different filters can be selected and activated independently for each channel. These are high-pass type filters with amplification of 6 dB, 12 dB, 18 dB and 24 dB per octave.

The MHA test window is illustrated below.

Filter ch.1				Filter ch.2			
12 dB				--			
VU-meter VU-meter 							
Chann. 1	MIC		Chann. 2		MIC		
45	OUTPUT AC	EXT1 INPUT	INPUT EXT2	AC	OUTPUT	30	
dB HL	SIDE	EXT2	LEFT	SIDE	dB HL		
FILTER CH.1		FILTER CH.2					

MHA test window

The filters active on each channel are displayed at the top of the window, and the two VU-meters at the bottom.

If the INT input is selected, the window also shows the speech material, the name of the list, and the word presented to the patient. To change the speech material, press button MATERIAL.

The buttons FILTER CH.1 and FILTER CH.2 are used to select the type of filter applied to the corresponding channel 1 and 2, or to disable the filter.

As in the case of the Stenger test, no results are saved for the MHA, which means therefore that reports cannot be printed or sent to a computer.

TEN TEST

The TEN test can be used to assist the detection of a dead region in the cochlea. The test is designed to be quick and easy to administer and hence suitable for use in clinical practice. The development and validation of the test were made by Dr Brian C. J. Moore at the University of Cambridge.

The test involves measuring the threshold for detecting a pure tone presented in a background noise called "threshold-equalizing noise" (TEN).

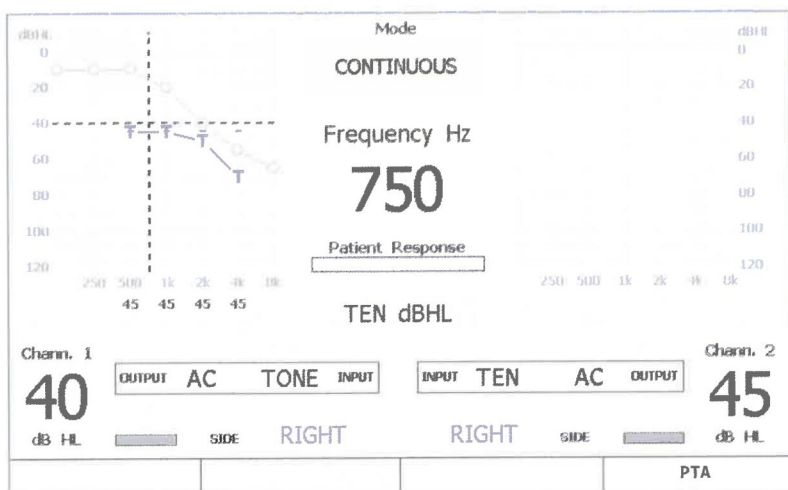
To perform the test, it is mandatory to previously assess the patient's pure-tone threshold levels between 500 and 4000 Hz. After the pure-tone audiogram is obtained, the user can access the TEN test screen from the main menu and see it displayed on the background of the graph. During the execution of the exam, the noise must be added to each frequency of the pure-

tone signal with a level at least 10 dB above that of the threshold. Both the tone and the noise are presented to the same ear of the patient. So far, if the obtained masked threshold is 10 dB or more above that of both the threshold and the TEN noise, the cochlea is considered “dead” at that frequency.

On Piano, the TEN test has its dedicated screen accessible from the main menu. Here, the user can set the side to be stimulated and the intensities relative to the stimuli and noise. Similar to pure-tone audiometry, during TEN test it is possible to present a pulsed stimuli, enable the tracking or lock options.

Stored masked thresholds are displayed on the audiogram using “T” symbols and the masking level indicated below.

Following, a TEN test window is illustrated.



TEN test window

QUICKSIN TEST

Difficulty with hearing in background noise is a common complaint among hearing-impaired persons. The measurement of SNR loss (signal-to-noise-ratio) is important because speech understanding in noise cannot be reliably predicted from the pure tone audiogram. (Killion & Niquette, 2000).

The Quicksin™ test was developed to provide a quick estimate of SNR loss and it is comprised of sentences recorded in four-talker babble. Each of the lists has six sentences with five key words per sentence, one sentence at each

SNR of 25, 20, 15, 10, 5 and 0. SNR loss can be estimated scoring the five key words in each sentence, giving one point to each word repeated correctly.

QuickSIN™ sentences are loaded in the flash memory of the audiometer which is organized as described in *CHAPTER 6: Speech audiometry*. Before playing a list from the flash memory, the required material must first be selected by pressing the MATERIAL function button. Once the QuickSIN material has been selected, the sentences of the first list in the folder are displayed on the screen and the list can be played by pressing the PLAY button located at the top left of the keyboard. If there is no audio material being played currently, pressing PREVIOUS/NEXT buttons will bring up the precedent/following list.

Once the desired list has been selected and is playing, PREVIOUS/NEXT buttons can be used to jump back/forward among the sentences of the list, currently played sentence is highlighted in the audiometer's screen. Each sentence is presented at pre-recorded signal-to-noise ratios which decrease in 5-dB steps from 25 (very easy) to 0 (extremely difficult). At the end of each sentence the list pauses and the score of the sentence can be stored using CORRECT/INCORRECT buttons: CORRECT button to increase the score and INCORRECT button to decrease it. Pressing PLAY button will advance to next sentence and play.

After all six sentences are scored, SNR loss can be estimated and saved using STORE button. To interpret the SNR loss score, see the following table.

SNR LOSS	DEGREE OF SNR LOSS	EXPECTED IMPROVEMENT WITH DIRECTIONAL MIC
0-3 dB	Normal/near normal	May hear better than normal hear in noise
3-7 dB	Mild SNR loss	May hear almost as well as normals hear in noise
7-15 dB	Moderate SNR loss	Directional microphones help. Consider array mic
>15 dB	Severe SNR loss	Maximum SNR improvement is needed. Consider FM system

QuickSIN™ lists can be presented through headphones (AC) or on loudspeakers (FF). Presentation level can be set to 70 dB HL for pure tone average (PTA) ≤ 45 dB HL, for PTA of 50 dB HL or greater set the attenuator dial to a level that is judged to be "loud, but OK".

QuickSIN™ window is illustrated below.

VU-meter		VU-meter	
-20 0 3		-20 0 3	
5	SNR 25	a WHITE SILK JACKET goes with ANY SHOES	
5	SNR 20	the CHILD CRAWLED INTO the DENSE GRASS	
4	SNR 15	FOOTPRINTS SHOWED the PATH he TOOK up the BEACH	SNR loss
3	SNR 10	a VENT NEAR the EDGE brought in FRESH AIR	5,5
2	SNR 5	it is a BAND of STEEL THREE INCHES WIDE	
1	SNR 0	the WEIGHT of the PACKAGE was SEEN on the HIGH SCALE	
Mat Standard		List 01 List	
Chann. 1			
70	OUTPUT AC INT INPUT	Secondary channel disabled	
dB HL	FF		
	SIDE RIGHT		
MATERIAL			

QuickSIN™ window

Before starting QuickSIN™ test, adjust the level of gains using the 1-kHz calibration tone so that the VU-meters of the two channels read “0”. Once the gain values for QuickSIN™ input have been set, they are saved internally on the audiometer, and remain stored even after the instrument has been switched off.

QuickSIN™ material include:

- 1-kHz calibration tone
- 12 standard lists with speech and 4-talker babble noise combined on the same channels for basic SNR loss testing.
- Practice lists A, B and C that can be used to familiarize the patient with the task. These lists are not equivalent to the standard lists and cannot be used to calculate SNR loss.
- 12 standard split-track lists recorded with sentences on channel 1 and babble noise on channel 2. These lists can be used to verify the effectiveness of hearing aids that have switchable directional microphones. Two types of demonstrations are possible and can be selected using the MODE function button:
 - o Subjective: both speech and noise levels can be manually adjusted. Having the patient switch back and forth between OMNI and directional positions on the hearing aid/s gets a basic measure of directional benefits. In this mode SNR loss can't be estimated.

- **Objective:** once the speech level has been set, the noise level is automatically adjusted so that the SNR decreases from 25 to 0 by 5 dB for each succeeding sentence. In this mode lists can be scored to obtain SNR loss, and SNR loss obtained in OMNI and Directional positions can be compared.
- 12 HFE lists recorded with 30 dB high-frequency emphasis (HFE). The HFE is used to make speech sounds audible for persons with ski-slpoe loss.
- 12 HFE-LP lists recorded with HFE plus 3-kHz low-pass brickwall filter, these lists can be used in combination with the HFE lists to predict the outcome of fitting hearing aids with extended HFE.

How to enable the QuickSIN™ test

In order to enable the QuickSIN™ test, access the test window from the main menu, press the ENABLE function button and fill in the licence number.

CHAPTER 8:

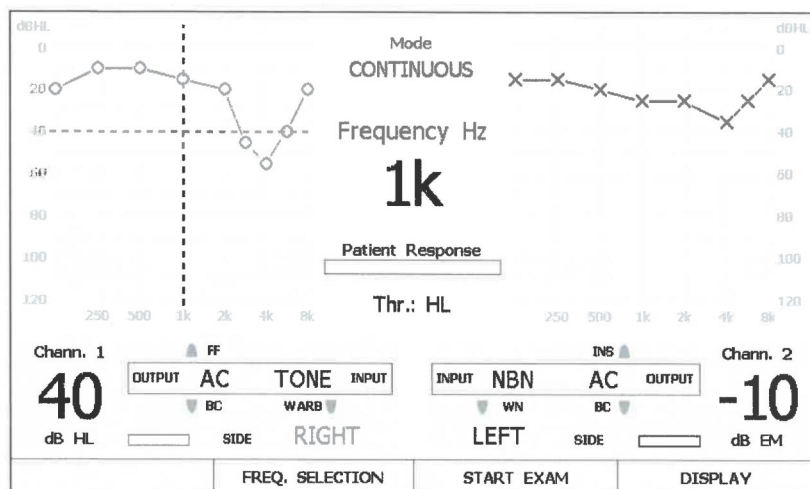
Automatic audiometry

The Piano audiometer features two automatic audiometry tests: Auto Threshold and Békésy audiometry (only Piano Plus). The current chapter describes these two exams.

AUTO THRESHOLD

Auto Threshold pure tone audiometry allows the operator to establish the hearing threshold for different frequencies by way of an automatic procedure. The method applied is the Hughson-Westlake technique, as adapted by Martin, which provides a modified and shortened version of the method indicated in ISO standard 8253-1 (described in CHAPTER 5: Pure tone audiometry) for determining the AC threshold without masking.

To run the Auto Threshold test, the relative window must be opened from the main menu. As long as the automatic procedure is not initiated, a classic pure tone audiometry session can still be performed from the Auto Threshold window, using either air or bone conduction. The Auto Threshold test window is illustrated below.



Auto Threshold window

Pressing the *FREQ. SELECTION* button, another window opens, from which to select the frequencies that will be examined during the course of the test. Bear in mind that the 1 kHz frequency cannot be deselected. The selection or omission of each frequency is a parameter that will be retained even after the instrument has been switched off. The following frequencies are enabled initially: 250 Hz, 500 Hz, 1 kHz, 2 kHz, 4 kHz and 8 kHz.

To begin the test, simply press the *START EXAM* button. The test finishes automatically once all the enabled frequencies have been analysed for both ears. The procedure can be interrupted if necessary, by pressing the *END EXAM* button (which replaces *START EXAM* once the test is in progress). After pressing *START EXAM*, a message will appear warning the operator that any air-conduction-related threshold data saved previously will be erased.

The Auto Threshold test comprises an initial familiarization step serving to train the patient in the threshold identification procedure. The patient must press the response button every time the stimulus is heard, and release the button thereafter. In particular, the stimulus is presented for a duration of 1.7 seconds, followed by a pause of random duration between 1.7 seconds and 2.5 seconds.

The adopted method of determining the threshold envisages an increase of 5 dB in the level of the stimulus, and a reduction of 10 dB. The threshold is

established as the level for which at least 2 positive responses are elicited from the patient over 3 sequences.

During this initial step, the message *FAMILIARIZATION* appears in the display. The stimulus presented to the patient is generated at a frequency of 1 kHz and an initial intensity of 40 dB HL (which cannot be changed). Once the threshold has been identified, the familiarization step ends, and the test begins automatically.

The first frequency examined in the Auto Threshold sequence is 1 kHz. Once the hearing threshold has been identified for this frequency, the test passes on to the next frequency. The order in which the selected frequencies are analysed is as follows: first, frequencies higher than 1 kHz, in ascending order, then frequencies lower than 1 kHz, in descending order, and finally, the 1 kHz frequency again.

Once all these frequencies have been analysed for one ear, the test is repeated automatically on the other ear.

In practice, if the patient is unable to hear a stimulus signal even at the maximum permissible level for a given frequency and after it has been presented 10 times, the signal in question will be identified as "not heard".

The audiogram will be updated in real time during the course of the test, to show the results obtained.

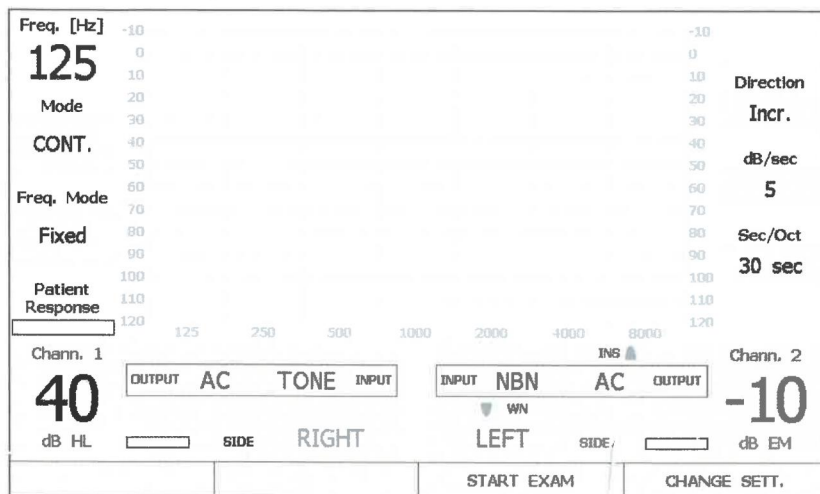
BÉKÉSY AUDIOMETRY (ONLY PIANO PLUS)

The Békésy test is an automatic audiometry test, which allows to gather many diagnostic information; such information is derived mainly from the comparison between the tracings obtained using a continuous tone and an interrupted tone.

In the Békésy test, the patient directly controls the intensity of the tone, decreasing or increasing it by respectively pressing or releasing the response button. The test performs the automatic detection of the hearing threshold on a selected set of frequencies or within a selected range of frequencies, with the frequency of the tone changing smoothly from the lower to the upper bound.

Comparing the tracing obtained using a continuous tone with that using an interrupted tone, Jerger classified the test results (Békésy curves) in four different categories (see Bibliography for references to literature).

The Békésy test window is illustrated below.



Békésy audiometry window

Besides the current frequency, on the left portion of the display are the two key parameters of the test, i.e.:

- The tone presentation mode, which can be:
 - o Continuous;
 - o Pulsed at 2 Hz;
 - o Pulsed at 1 Hz with LOT pulses (*Lenghtened Off Time*: pulsed tone with duty cycle reduced to 20% instead of 50%);
- The frequency scanning mode; the available options are:
 - o "Fixed": the frequency of the tone moves directly from one to the next selected one (or prior, if the scanning direction is descending);
 - o "Sweep": the frequency of the tone changes continuously (in fact, in steps of 1/24 octave) during the examination, from the lower to the upper selected bounds (or vice versa, if the scanning direction is descending).

On the right of the graph you will find the other exam parameters, i.e.:

- The frequency scanning direction: ascending or descending;
- The tone intensity changing rate (dB per second);
- The tone frequency changing rate (seconds per frequency in Fixed mode, seconds per octave in Sweep mode).

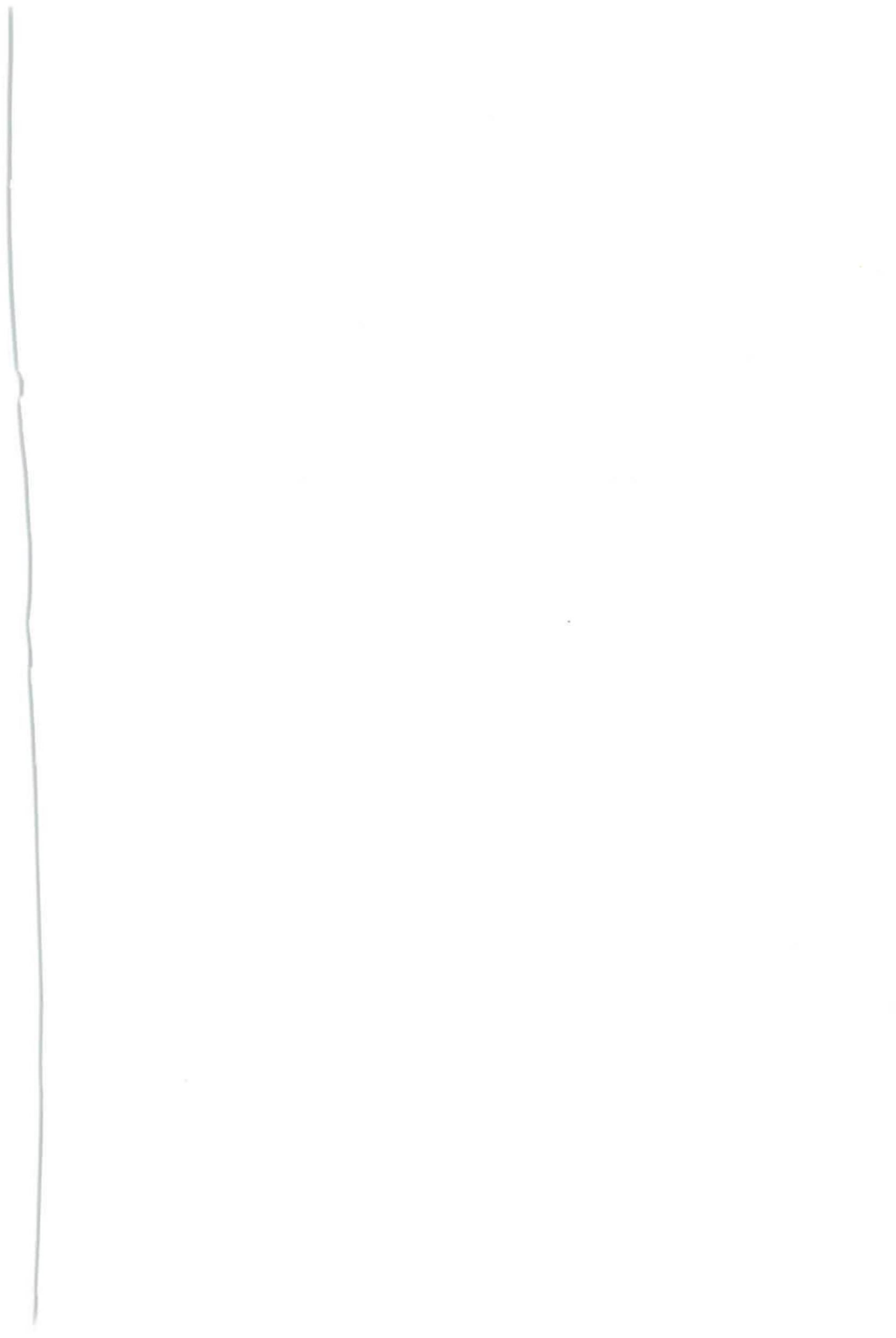
These parameters are different for the two frequency scanning modes (Fixed and Sweep). To change them, you need to press the function button CHANGE SETT. and then touch the relevant area on the screen. After pressing CHANGE SETT., you can also select, just by touching the graph,

the frequencies (Fixed mode) or the range frequencies (Sweep mode) to be analyzed during the examination. These frequencies will be highlighted on the graph.

To start the test, press the relevant function button: once started, it is not possible to change the test parameters; the tracing is updated in real time. Depending on the tone presentation mode, the tracing is plotted with a continuous or dotted line (in case of LOT interrupted tone, the dots are more sparse).

To terminate the exam in advance, press the STOP function button.

On the displayed graph, you will find all the tracings of the exams conducted on the same ear. If you perform an exam with the same selection of side/transducer/stimulation mode, the previous one will be lost.



CHAPTER 9:

Pediatric Audiometry

The VRA version of the Piano audiometer allows to execute, in addition to those described in the previous chapters, the exams of pediatric audiometry with visual reinforcement (*Visual Reinforcement Audiometry*, VRA) or conditioning (*Conditioned Play Audiometry*, CPA), described in this chapter.

PEDIATRIC AUDIOMETRY WITH PIANO VRA

The pediatric audiometry exam involves the use of visual stimuli (or *reinforcements*) in the manner described below. With the audiometer Piano you can use two types of reinforcements: up to three animated toys, directly connected to the audiometer, and up to three LCD displays (positioned on the front and sides of the baby), on which you can visualize images and animations. For the latter mode of stimulation, it is necessary to connect the audiometer to a computer, on which Maestro software has to be installed (refer to *Maestro – Impedance-Audiometry functionalities – User manual*, for more details).

The Piano VRA audiometer allows to execute the pediatric audiometry through the two traditional approaches, i.e. the VRA (*Visual Reinforcement Audiometry*) and the CPA (*Conditioned Play Audiometry*), here below described.

CPA (Conditioned Play Audiometry)

This mode of examination is used with children aged 2-3 years, and does not particularly differ from the traditional pure tone audiometry. An auditory stimulus is presented, and the child must press the button if he can hear it. The patient button used in this test is not the classic hand-button used with the adult, but rather the large desktop button supplied with the Piano VRA audiometer, which has to be connected to the patient response auxiliary input of the audiometer (PAT. RESP AUX).

If the child's answer is correct (i.e., if he presses the button after a stimulus is delivered), he receives a "bonus", which can be a picture or an animation on the display or the activation of a toy. The purpose of the bonus is keeping

the baby's attention, and therefore his collaboration, as high as possible during the examination.

VRA (Visual Reinforcement Audiometry)

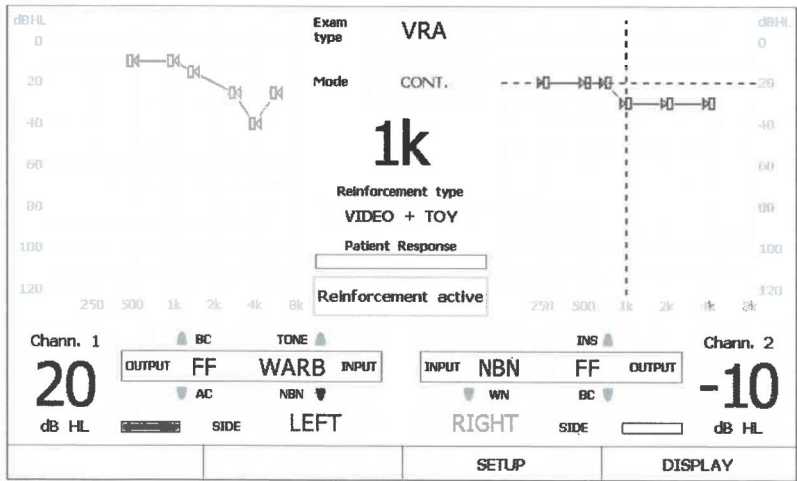
Very young children, especially those with severe hearing impairment, are extremely uncooperative, so it is not possible to use the CPA approach for audiometric testing. In these cases, you should use the VRA methodology.

The VRA exam needs an initial training; during this stage, the operator sends to the child a clearly audible sound stimulus, and then a visual stimulus (the *reinforcement*), thus creating a reflex in the child, who, if he hears the sound, will turn his head looking for the reinforcement.

After the training, when the reflex is established, you can begin the actual examination: the operator will alternate the sound stimuli and the reinforcements, looking at the baby's reaction to decide if he could or could not hear the stimulus, thus determining the hearing threshold for each frequency.

PERFORMING THE EXAM

To perform the pediatric audiometry test with Piano, enter the relevant window from the main menu. Since the graphical interface, shown in the picture below, is very similar to that of the pure tone audiometry, the standard functionalities will not be here described (you can refer to Chapter 5: Pure Tone Audiometry).



Pediatric audiometry window

In the central area of the display you will find the examination type currently selected, i.e. the VRA or the CPA tests.

The only difference between the two tests regards how the visual reinforcement is activated: in the VRA test is the operator who decides when to activate the reinforcement, while in case of CPA the reinforcement is automatically activated when the patient presses the button following the delivery of a stimulus.

There are two types of reinforcement: the animated toys enclosed in a darkened box and the animations / images on the LCD display, the latter available only if the audiometer is connected to a computer on which Maestro software is installed (refer to *Maestro – Impedance-Audiometry functionalities – User manual* for more details). In the center of the display, below the current frequency label, there is the currently selected type of reinforcement; to modify it, touch the yellow box on the screen. The three available options are: toy, display, toy and display simultaneously.

In the central part of the display the activation of the reinforcement is indicated. As written before, the manual start of the reinforcement is only possible during a VRA examination, while in the CPA exam it is automatic. To facilitate the operations of activation and deactivation of the reinforcement, this is controlled by the patient hand-button used in the traditional PTA exam, connected to the “PAT. RESP. MAIN” input socket. The table button used by the child in the CP exam is in fact connected to the auxiliary input socket of the audiometer (marked with “PAT. RESP. AUX.”). Note that, when a video reinforcement is selected, this is activated only if the audiometer is connected to the PC and Maestro software is open on the pure tone audiometry screen with the option *Pediatric* selected (refer to *Maestro – Impedance-Audiometry functionalities – User manual* for more details). The “SETUP” function button at the bottom of the screen allows you to modify some settings for the currently selected type of examination (i.e., VRA or CPA). These settings are stored in the device internal memory and maintained in each subsequent restart of the instrument.

The settings shared by the two exam types are:

- The duration of the reinforcement, between 1 and 10 seconds; it is possible to manually stop it before.
- The toy to activate; you can choose between the right, the left and the central one. In the VRA examination it is also possible to select the “ipsilateral” option: in this case the toy to animate will be automatically selected, and will correspond to the side of stimulation.
- The use of continuous or blinking light to illuminate the toy.
- Enable / disable the animation of the toy.

In the VRA test it is also possible to change the way you use the button to activate the reinforcement:

- Reinforcement is only active when the button is held down
- Reinforcement is activated by pressing the button and stops automatically at the end of the time span set, or by pressing the button again.

In the CPA test, it is possible to set the period when the patient's response is considered valid. This period is calculated from the end of the acoustic stimulus, and can be between 1 and 5 seconds. The child's response is therefore considered valid (and thus the reinforcement automatically activated) if he presses the button when the tone is still active or within the end of the valid period as determined.

CHAPTER 10:

Interface with the computer

Piano audiometer is able to interface with a computer by way of a USB connection, for the purpose of copying tests to the computer hard disk. Software Maestro must be installed on the computer *with or without proprietary database* or as *Noah module*. Refer to *Maestro – General Functionalities – User Manual* for a detailed description of how to install Maestro on your computer and to *Maestro – Impedance-Audiometry functionalities – User manual* for more information about how to use Piano audiometer by the computer.

CONNECTION TO PC

Piano audiometer is connected to one of the USB ports on the computer using the cable supplied (standard USB A/B cable). The connection is plug-and-play, with no special drivers required for installation purposes: a few seconds after plugging in, the operating system will recognize the device and install the drivers automatically. The installation is complete when the following message appears at the bottom right of the screen:



Piano audiometer is compatible with computers using a Microsoft Windows 32 or 64 bit operating system, XP SP3 or later.

CHAPTER 11:

Settings

Piano audiometer has a number of configuration parameters that can be changed in the settings window. This chapter describes the parameters available, and how to change them.

SETTINGS WINDOW

To access the settings window, simply press the SETUP function button shown on the main screen of the instrument.

Once the settings window appears, the left-hand knob can be used to scroll through the available items, whereas to change the value of the selected item, either rotate the right-hand knob or press the CHANGE button. Certain items, such as setting of the date and time, require access to a specific window if changes are to be made; in these cases, press the SELECT button to access the changes window.

The settings window also includes an INFO function button, which opens a window containing certain items of information on the audiometer such as the serial number and the version of the internal software.

When exiting the settings window, if at least one parameter has been changed, the instrument will prompt whether to save the new settings or maintain the previous settings.

USER-SETTABLE PARAMETERS

All configuration parameters that can be set by the user are listed below. A default value is indicated for each parameter. This represents the factory setting.

Not all of the items listed are available on every model.

Language

Selection of the interface language used by the instrument.

Default value: English

Link BC symbols

Enables / disables the display of lines interconnecting bone conduction symbols in speech audiometry.

Default value: No

Symbol for BC-Right

Selects the symbol for pure tone audiometry using bone conduction, right ear. The symbols that can be selected are:

< a)

b) >

Default value: <

Symbol for masked BC-Right

Selects the symbol for pure tone BC audiometry with masking (right ear). The symbols available when selecting the symbol identified by letter *a* for BC right are indicated in the following illustration by the letters *c* and *d*; if the symbol selected for BC right is that identified by letter *b*, then the symbols available are *e* and *f*.

c) ◁ d) □

e) ▷ f) ▢

Default value: □

Symbol for UCL

Selects the symbol for UCL threshold in the pure tone audiometry, right ear.
The symbols that can be selected are:

- a) **E**
- b) **M**
- c) **L**

Default value: **E**

High contrast display

Enables / disables the display of test screens with a high level of contrast. In particular, the normally grey background of the fields showing channel status information (level, input, output, side, activation) changes to white, in high contrast mode.

Default value: No

Primary channel

Sets the primary channel of the device (that used for presenting the tone in PTA)

Default value: 1

AC transducer

Selects the type of transducer used for AC at the standard frequencies. The available options are Telephonics TDH-39 or RadioEar DD45, ER-3 or ER-5 insert-type earphone and Sennheiser HDA-200 or HDA-300 (only Plus model).

Default value: TDH-39 (or DD45)

HF max frequency (only Piano Plus)

Set the higher available frequency in HF audiometry. Available values are 16 and 20 kHz.

Default value: 16 kHz

FF intensity range

The intensity range for free field pure tone and speech audiometry tests, in other words the maximum output values; can be normal (Norm.) or extended (Ext.). See Appendix A for details of maximum values in the two different configurations.

Default value: Normal

Default intensity (dB)

In pure-tone audiometry, selects the default level for the stimulus on the primary channel, in other words the intensity at which channel 1 is set when changing the stimulation side, the output, the input or the frequency. The initial intensity can be set between 0 and 60.

Default value: 40 dB

Maintain intensity

If enabled, the level of the stimulus on the primary channel in pure-tone audiometry stays the same (i.e. does not revert to the default value) when changing the stimulation side, output, input or frequency.

Default value: No



Maintaining the previous intensity of the stimulus when changing frequency, transducer or stimulation side can result in potentially harmful signals being presented to the patient.

Beep for automatic tests

Enables or disables the beep generated at the end of automatic test sequences.

Default value: Yes

Beep at patient response

Enables or disables the beep generated when the patient presses the patient response switch.

Default value: No

Auxiliary response switch

Select if the audiometer is supplied with the auxiliary response button.

Default value: No

PTA at start-up

If set to Yes, the instrument will go directly to the pure-tone audiometry window when powered up, otherwise the main menu will appear to allow selection of the different test options.

Default value: No

Frequency selection

Access to the frequency selection window.

In this window you can enable / disable the frequencies to be tested in pure-tone audiometry.

Frequency jump mode

Sets the sequence in which frequencies are scanned for pure-tone audiometry, when automatic jump mode is selected.

There are 2 options:

- 1) 8k → 125: saving the threshold at 8 kHz (or 12.5 kHz if this is the active frequency), the program jumps to 125 Hz, followed by each of the higher frequencies.
- 2) 8k → 1k: saving the threshold at 8 kHz (or 12.5 kHz if this is the active frequency), the program jumps to 1 kHz, then moves sequentially through the lower frequencies, down to 125 Hz. This is the frequency scanning method prescribed by standard EN ISO 8253-1.

Default value: 8k → 1k

Automatic frequency jump

In pure-tone audiometry, enables / disables automatic transition to the next frequency after a value has been saved by pressing the STORE button. The order in which frequencies are scanned will depend on the "Frequency jump mode" parameter, described below.

Default value: Yes

Single pulse length

Tone duration in “single pulse” presentation mode.

Default value: 1000 ms

Custom pulse period

Pulse period length in case of pulsed presentation with custom period.

Default value: 1500 ms

Enables independent channels in PTA

Activate the independent channels function during PTA.

Display masking values

If enabled, it allows to see during the pure tone exam, under the audiogram, the level of the applied masking signal.

Default value: No

Speech score mode

Selects the method of calculating the percentage of correct responses in speech audiometry.

Mode 1: calculates the percentage of correct responses in relation to the total number of responses given. More exactly, indicating the words recognized successfully by the patient as *correct*, and the number of words not recognized by the patient as *incorrect*, the *percentage* is calculated as follows:

$$\text{percentage} = 100 * \text{correct} / (\text{correct} + \text{incorrect})$$

Mode 2: calculates the percentage of correct responses in relation to the *total number of words* in the list. This parameter is configurable from the settings window.

The *percentage* in this instance is calculated as:

$$\text{percentage} = 100 * \text{correct} / \text{total number of words}$$

Default value: Mode 1

Speech words number

Sets the total number of words in the lists; this parameter is used only when Mode 2 is selected as the method of calculating the outcome of a speech audiometry test. The number of words can be set between 1 and 20.

Default value: 10

Pause after each word

If set to Yes, during the playback of the internal speech material, the system automatically pauses the audio track after each of the word has been presented to the patient.

Default value: No

Enable WRS single point

Option for measuring the Word Recognition Score as a single point instead of using a graph. Furthermore, if enabled, you may select the same input for both channels during the speech audiometry.

Default value: No

Turn off monitor after speech

If enabled, sets the intensity of the monitor signal to zero when the speech audiometry window is closed. When the window reopens, the previous levels will be restored (only if the user never enters the monitor volumes adjustment window from not speech-like exams).

Default value: Yes

Enable EQ filter on AC

Enables / disables the free field equivalent filter applied to AC speech audiometry output signals when using TDH-39 or DD45 headphones.

Default value: No

Live speech microphone

Selects the microphone input used to perform the live speech audiometry: MIC or TALK OVER. After having selected the input, the microphone must be plugged in the corresponding connector on the rear panel.

Default value: TALK OVER

Assistant monitor (only Piano Plus VRA)

Enables / disables the assistant monitor feature that allows a second operator to hear the stimulus sent to the patient and to communicate with the clinicians through the talk-over function.

Default value: No

Print patient data header

Enables / disables printout of the heading with details of the patient.

Default value: Yes

Clinic data menu

Customization of the print header with two available rows for characters. This option can be disabled.

Settings protected by password

If enabled, access to settings screen is protected by the password "010113".

Default value: No

Calibration menu

Access to the calibration window of the audiometer.

Date and time menu

Access to the window in which the date and the time are set. The time is written, by default, in the 24-hour notation: by accessing this windows it is possible to switch to the 12-hour time format.

Touch screen calibration

Access to the window for the touch screen calibration.

Service tests

Access to the window from which service tests are run on the instrument. For maintenance purposes, only.

CHAPTER 12:

Maintenance

Piano audiometer does not require any special periodic maintenance other than calibration and normal cleaning, both of which are described in this chapter.

The instrument must be switched off and disconnected from the power supply before commencing any kind of cleaning operation.



The inspection and servicing of internal components must be left entirely to technicians approved by Inventis srl.



Transducers are manufactured utilizing ultra-fragile diaphragms that could be damaged in the event of impact. Handle with care during maintenance operations.

CLEANING

To prevent the accumulation of dust on the audiometer, always cover the instrument with the protective cloth when not in use. Dust the audiometer regularly to ensure it is kept clean.

All parts not mentioned specifically in the previous section can be cleaned using a lint-free soft cloth moistened with a solution of water and mild detergent; in case of sanitization wipe the cloth with hydrogen peroxide at a 3% concentration.

PERIODIC CHECKS

To maximize the audiometer life and all of its accessories service life, it's suggested to daily do the following tests.



The tests must be done with the audiometer in its installation position.

- Before switching on the instrument, check that all the contacts are perfectly connected and that the cables and/or connectors as well as all other elements do not appear to be broken or damaged externally
- Check subjectively that the air conduction and bone conduction output is equal on both channels and all frequencies, In order to do this 10 or 15 dB, just enough to hear is applied. The person who carries out this check should have good hearing
- Check at a level of 60dB in AC and 40dB in BC that there is no distortion, noise or parasitic signals in any of the frequencies
- Check that the interrupter key(s), the patient response switch(es) and the keyboard indicators function correctly
- Check that the attenuator knobs function correctly without noises or interference between channels
- Check the speech audiometry inputs by doing a speech test with every speech input
- Check the headband strain of headset and of bone vibrator
- Check the communication with the patient



Should any accessory not function correctly, consult Appendix D "Troubleshooting".

It's basic also check that the calibration interval has not elapsed: the expiry of the interval is indicated at the bottom of the main presentation screen.



Calibration must be entrusted to technicians approved by Inventis srl. The operation should be performed at least once every 12 months, and whenever a transducer is replaced.

MAINTENANCE OF TRANSDUCERS



Do not use liquids or sprays to clean the audiometer.

Do not allow dust to collect on the transducers. Also:

- The headphone cushions are made of biocompatible material, but are not sterile: whenever the headphones are to be worn by a new patient, the cushions must be wiped with a hypoallergenic proprietary disinfectant, following the maker's instructions. This will prevent the spread of infection and guarantee the biocompatibility of the material.
- The eartips of ER-3 and ER-5 insert earphones are made of biocompatible material and disposable: use once only and dispose of in accordance with current health and safety regulations.



The eartips of insert earphones are not sterile. The use of unsterilized earpieces can cause ear infections.

TOUCH SCREEN CALIBRATION

If the device touch screen does not respond accurately to your commands, it will most likely require a recalibration; this operation is very simple and fast. You must first enter the touch screen calibration window through the device settings window. Once entered, you will see four crosses in sequence on the screen: touch each cross in its center, trying to this as accurately as possible. At the end of this operation, the touch screen is calibrated.

If the touch screen is so much out of calibration (e.g. as a result of a collision) that it does not allow you to access to the calibration window, you can open it even by pressing simultaneously the BACK and HELP function keys during the ignition phase, before the Inventis logo is displayed on the screen.

REPLACEABLE PARTS

The transducers and accessories can be disconnected from the device. Should a fault develop in any one of these devices, the audiometer must be switched off and isolated from the power supply, and the defective item then disconnected from the device.



All accessories of the audiometer are designed specifically for use with the device. Only accessories supplied by Inventis should be connected to the audiometer.

LOADING THE PRINT PAPER

To load a new roll of paper in the printer, the rear cover must first be opened and the empty spool removed.



The heat-sensitive side of the paper is located externally of the winding mechanism: the paper must be positioned so that the heat-sensitive face does not come into contact with the rubber pinch roller.

Raise the green lever and offer the paper to the bottom part of the roller. Feed the paper through until it emerges from the top part at the required height. Lower the green lever.



Make certain that the paper is correctly aligned. If this is not the case, follow the manual loading instructions to correct the alignment.

Slip the paper through the slot in the cover, and close the cover.

REPAIRS AND TECHNICAL ASSISTANCE

Before contacting the service department, make certain that all the possible solutions in the "Troubleshooting" appendix have been tried.

All the parts being returned to the manufacturer for repair and service shall be sterilized or disinfected and put in a transparent bag hermetically closed. Should the instrument need to be sent to the Inventis service department or returned to the dealer, it is important that the original packing should be used, and that all accessories and transducers are enclosed.

APPENDIX A:

Technical specifications

Classification

Type 1 pure tone audiometer (EN 60645-1 / ANSI S3.6)

Type A or A-E speech audiometer (EN 60645-2 / ANSI S3.6)

Plus model : HF audiometer (EN 60645-4 / ANSI S3.6)

AVAILABLE SIGNALS		
<i>Type</i>	<i>Basic</i>	<i>Plus</i>
Pure tone	●	●
Warble tone	●	●
2 external inputs for speech audiometry (EXT1 and EXT2)	●	●
MIC input for live speech audiometry	●	●
Internal input (flash memory) for speech audiometry	●	●
Narrow-band noise (NBN)	●	●
White noise (WN)	●	●
Speech noise (SN)	●	●
Threshold equalizing noise (TEN)	●	●

SIGNALS SPECIFICATIONS	
Attenuators step	1 and 5 dB
Presentation mode	Continuous Single pulse with selectable length Pulsed, with rate of 0.5, 1, 2 Hz or selectable
Frequency accuracy	0,1 %
Intensity accuracy	±3 dB between 125 Hz and 4 kHz ±5 dB above 4 kHz
Total Harmonic Distortion (THD)	AC: less than 2,5 % BC: less than 5,5 %
Warble tone	Frequency of the modulating signal: 5 Hz Modulation waveform: sine wave Modulation range: ±12%
NBN	Band: ½ octave, i.e.: - lower cut-off frequency $f_l = f / 1.1892$ - upper cut-off frequency $f_u = f \cdot 1.1892$ where f is the centre frequency
WN	Lower cut-off frequency: 100 Hz Upper cut-off frequency: 24 kHz
SN	As specified in EN 60645-2 §13
External signals	EXT1 and EXT2 input: max 3 Vrms
TEN	Lower cut-off frequency: 350 Hz Upper cut-off frequency: 6500 Hz

AVAILABLE OUTPUTS		
<i>Output</i>	<i>Basic</i>	<i>Plus</i>
Air conduction (TDH-39 or DD45 headphones)	●	●
Air conduction (ER-3 or ER-5 insert earphones)	●	●
Air conduction (HDA-200 or HDA-300 headphones)	-	●
Bone conduction (B-71 bone vibrator)	●	●
Free field	●	●
Insert masking earphone	●	●

**PURE AND WARBLE TONE
AVAILABLE FREQUENCIES AND MAXIMUM INTENSITIES**

Freq. (Hz)	AC TDH39 DD45 (dB HL)	AC HDA200 HDA300 (dB HL)	AC ER-3 (dB HL)	AC ER-5 (dB HL)	BC (dB HL)	FF (*) (dB HL)
125	80	85	90	90	-	75
250	100	100	105	100	45	85
500	120	110	110	110	65	95
750	120	110	115	120	70	95
1,000	120	110	120	120	75	95
1,500	120	110	120	120	80	95
2,000	120	110	120	115	80	95
3,000	120	110	120	115	75	95
4,000	120	105	110	110	75	95
6,000	110	100	100	100	55	90
8,000	100	90	90	90	50	85
9,000	-	90	-	-	-	80
10,000	-	90	-	-	-	80
11,200	-	90	-	-	-	80
12,500	-	80	-	-	-	80
14,000	-	70	-	-	-	80
16,000	-	50	-	-	-	50
18,000	-	110 dB SPL	-	-	-	-
20,000	-	110 dB SPL	-	-	-	-

(*) The maximum levels refer to the “normal” intensity range for free field. In case of extended range, add 10 dB to each value (see *Chapter 12: Settings* for switching between the two options).

**SPEECH AUDIOMETRY
MAXIMUM INTENSITIES**

	AC TDH-39 DD45 (dB HL)	AC HDA-200 HDA-300 (dB HL)	AC ER-3 ER5 (dB HL)	BC (dB HL)	FF (dB HL)
TYPE A	100	90	100	55	Norm.: 75
					Ext.: 85
TYPE AE	80	90	100	55	Norm.: 75
					Ext.: 85

EXTERNAL SIGNALS LEVEL INDICATOR

Type of indicator	VU-meter
Dynamic range	+3...-20dB
Input Voltage at 0 dB	1.5 Vrms
Speed of the volume following	Increase: 60 dB/s Decrease: 60 dB/s

NARROW BAND NOISE (NBN) AND WHITE NOISE (WN) AVAILABLE FREQUENCIES AND MAXIMUM INTENSITIES

Freq. (Hz)	AC TDH39 DD45 (dB EM)	AC HDA200 HDA300 (dB EM)	AC ER-3 (dB EM)	AC ER-5 (dB EM)	BC (dB FL)	Insert earphon e (dB EM)	FF (*) (dB HL)
125	60	70	70	65	-	80	75
250	80	95	85	85	105	95	85
500	95	95	95	95	110	105	95
750	100	100	100	100	110	110	95
1,000	105	100	105	100	110	115	95
1,500	105	100	105	100	110	115	95
2,000	105	100	105	100	110	115	95
3,000	105	100	105	100	100	115	95
4,000	105	95	100	100	100	110	95
6,000	100	90	90	95	90	95	90
8,000	90	80	80	80	90	95	85
9,000	-	80	-	-	-	-	80
10,000	-	80	-	-	-	-	80
11,200	-	80	-	-	-	-	80
12,500	-	70	-	-	-	-	80
14,000	-	60	-	-	-	-	80
16,000	-	40	-	-	-	-	50
18,000	-	100 dB SPL	-	-	-	-	-
20,000	-	100 dB SPL	-	-	-	-	-

(*) The maximum levels refer to the “normal” intensity range for free field. In case of extended range, add 10 dB to each value (see *Chapter 12: Settings* for switching between the two options).

WHITE NOISE (WN) MAXIMUM INTENSITIES						
	AC TDH39 DD45	AC HDA200 HDA300	AC ER 3 ER 5	BC	Insert Mask	FF
WN	110 dB SPL	100 dB SPL	100 dB SPL	100 dB FL	100 dB SPL	Norm: 95 dB SPL
						Ext: 105 dB HL
WN Type A (speech)	90 dB EM	80 dB EM	80 dB EM	45 dB EM	80 dB EM	Norm: 75 dB HL
						Ext: 85 dB HL
WN Type AE (speech)	70 dB EM	80 dB EM	80 dB EM	45 dB EM	80 dB EM	Norm: 75 dB HL
						Ext: 85 dB HL

SPEECH NOISE (SN) MAXIMUM INTENSITIES						
	AC TDH39 DD45 (dB EM)	AC HDA200 HDA300 (dB EM)	AC ER-3 ER-5 (dB EM)	BC (dB EM)	Insert earphone (dB EM)	FF (dB HL)
Type A	90	75	80	45	80	Norm.: 75
						Ext.: 85
Type AE	70	75	80	45	80	Norm.: 75
						Ext.: 85

ACOUSTICAL SAFETY OF THE DEVICE	
Alert condition	Tone intensity higher than 100 dB HL (EN 60645-1, §5.2)
Safety measures in alert condition	1) The operator has to press "Higher dB" button to increase the intensity over 100 dB HL 2) Warning on the display 3) "Normally on" function disabled

COMPATIBLE TRANSDUCERS		
Type	Manufacturer	Model
Supra-aural headphones	Telephonics Corp.	TDH39
Supra-aural headphones	Radioear Corp.	DD45
Circum-aural headphones	Sennheiser elec. GmbH	HDA-200
Circum-aural headphones	Sennheiser elec. GmbH	HDA-300
Insert earphones	Etymotic Research Inc.	ER-3
Insert earphones	Etymotic Research Inc.	ER-5
Bone vibrator	Radioear Corp.	B71
Insert earphone for masking	Inventis srl	IME-100

PATIENT – OPERATOR COMMUNICATION	
Talk-over through: - Embedded microphone - External microphone (not included).	●
Talk back through: - Embedded speaker - External speakers (not included)	●
Patient response trigger	●
Secondary patient response trigger (for left / right discrimination)	opt.

AVAILABLE TESTS		
	<i>Piano Basic</i>	<i>Piano Plus</i>
Pure tone audiometry	●	●
Autothreshold	●	●
Speech audiometry	●	●
ABLB	●	●
MLB	●	●
SISI	●	●
DLI	●	●
Tone decay	●	●
Master hearing aid	●	●
Stenger	●	●
TEN test	●	●
QuickSIN	opt.	opt.
High Frequency audiometry	-	●
Multi-frequency audiometry	-	●
Békésy	-	●
MLD	-	●

DATA MANAGEMENT	
Integrated thermal printer (paper size: 112 mm)	Optional
Communication to the computer	USB
Management software	Maestro installed with or without proprietary database or as Noah module

DISPLAY	
Type	Graphical colour TFT LCD
Touch screen type	Resistive
Size	diagonal 7", 150 mm x 90 mm
Resolution	800 x 480
Available viewing modes	Normal / High contrast

POWER SUPPLY	
Power supply	External medical grade power supply (included), compliant to EN 60601-1 standard AC consumption: 100-240Vac 47-63Hz 0.9-0.34A DC output: 6V, 4,16A cont.

CALIBRATION	
Calibration validity	12 months

ENVIRONMENTAL CONDITIONS	
Use	Temperature: between 15°C (59°F) and 35°C (95°F) Relative humidity: between 30% and 90% (non-condensing) Pressure: between 700 hPa and 1060 hPa
Transport and storage	Temperature: between -10°C (14°F) and 50°C (122°F) Relative humidity: max. 90% non-condensing Pressure: between 500 hPa and 1060 hPa
Warm-up time	1 minute

MECHANICS	
<i>Models without the integrated printer</i>	
Size (LxDxH)	32 x 32 x 15 cm / 12.6 x 12.6 x 5.9 in
Weight (device only)	2.0 Kg / 4.4 lbs
Weight (including transducers and package)	4.4 Kg / 9.7 lbs
<i>Model with the integrated printer</i>	
Size (LxDxH)	32 x 39 x 15 cm / 12.6 x 15.4 x 5.9 in
Weight (device only)	2.5 Kg / 5.5 lbs
Weight (including transducers and package)	4.9 Kg / 10.8 lbs

SOCKETS ON THE REAR PANEL

<i>Description</i>	<i>Type</i>	<i>Connector</i>
Power supply	In	DC plug 2.5 mm
L and R headphones	Out	2 audio jack, 1/4" mono
L and R insert earphones	Out	2 audio jack, 1/4" mono
Bone vibrator	Out	Audio jack, 1/4" mono
Insert masking earphone	Out	Audio jack, 1/4" mono
L and R Free Field output	Out	2 RCA
Monitor headset	Out	Audio jack, 3.5 mm stereo
EXT1 and EXT2	In	2 RCA
Microphone for live speech tests	In	Audio jack, 1/4" mono
Patient response trigger (main)	In	Audio jack, 1/4" mono
Patient response trigger (secondary)	In	Audio jack, 1/4" mono
External microphone for talk-over or live speech tests	In	Audio jack, 3.5 mm mono
Patient microphone for talk-back	In	Audio jack, 1/4" mono
USB	In – Out	USB type B
<i>Only on Piano Plus</i>		
HF headphones	Out	Audio jack, 1/4" stereo
	Out	Audio jack, 3.5 mm stereo

SPECS OF INPUT FACILITIES

<i>Input</i>	<i>Connector type</i>	<i>Electrical property</i>
Power supply	DC PLUG 2.5mm	Internal pin +6V, external pin 0V
Patient response	Jack, 6.3mm mono	Switches 3V to logical input (switch current: 10mA) Impedance: 10K Ω
External input for speech aud.		Sensitivity: 3mV at max volume and 0Vu Impedance: 10K Ω Freq. response: 75-12000Hz +/- 3dB
Microphone	Jack, 6.3mm mono	Electret or 200 Ω dynamic microph. Impedance: 47K Ω Freq. response: 100-12KHz +/- 3dB Electret Bias: 2.2V trough 2.2K Ω
Talk over	Jack, 3.5mm stereo	
Talk back	Jack, 6.3mm mono	

SPECS OF OUTPUT FACILITIES			
<i>Output</i>	<i>Connector type</i>	<i>Available Voltage</i>	<i>Nominal Impedance</i>
TDH 39	Jack, 6.3mm mono	16V _{pp}	10 Ω
DD45	Jack, 6.3mm mono	16V _{pp}	10 Ω
ER-3 / ER-5	Jack, 6.3mm mono	16V _{pp}	10 Ω
B 71	Jack, 6.3mm mono	16V _{pp}	10 Ω
HDA 200	Jack, 6.3mm stereo	16V _{pp}	40 Ω
HDA 300	Jack, 6.3mm mono	16V _{pp}	23 Ω
Free Field (SPKF)	RCA	16V _{pp}	100 Ω
Insert mask	Jack, 6.3mm mono	16V _{pp}	32 Ω
Monitor	Jack, 3.5mm stereo	1V _{rms} by 32 Ω load	

SOUND ATTENUATION VALUES				
<i>Freq</i>	<i>TDH 39 / DD45 with MX41VAR or PN 51 cushion</i>	<i>ER 3 ER 5</i>	<i>HDA 200</i>	<i>HDA 300</i>
<i>[Hz]</i>	<i>[dB]</i>	<i>[dB]</i>	<i>[dB]</i>	<i>[dB]</i>
125	3	33.5	14.5	12.4
250	5	34.5	16	12.7
500	7	34.5	22.5	9.4
750	-	-	-	-
1000	15	35	28.5	12.8
1500	-	-	-	-
2000	26	33	32	15.1
3000	-	-	-	-
4000	32	39.5	45.5	28.8
6000	-	-	-	-
8000	24	43.5	44	26.2

REFERENCE EQUIVALENT THRESHOLD LEVELS									
Freq	TDH 39	DD45	ER 3	ER 5	B71*	HDA 200	HDA 300	FF	
	ISO 389-1 (ANSI S3.6)	Vendor Tech. Specifications	ISO 389-2 (ANSI S3.6)	ISO 389-2 [dB re 20 µPa]	ISO 389-3 (ANSI S3.6)	ISO 389-2 ISO 389-8 (ANSI S3.6)	Vendor Tech. Specifications	ISO 389-7 (ANSI S3.6)	
[Hz]	[dB re 20 µPa]	[dB re 20 µPa]	[dB re 20 µPa]	[dB re 20 µPa]	[dB re 1 µN]	[dB re 20 µPa]	[dB re 20 µPa]	[dB re 20 µPa]	
125	45	47.5	26	26	-	30.5	27		22.1
250	25.5	27	14	14	67	18	20		11.4
500	11.5	13	5.5	5.5	58	11	8		4.4
750	7.5 (8)	6.5	2	2	48.5	6	4.5		2.4
1000	7	6	0	0	42.5	5.5	2		2.4
1500	6.5	8	2	2	36.5	5.5	3		2.4
2000	9	8	3	3	31	4.5	0		-1.3
3000	10	8	3.5	3.5	30	2.5	-3		-5.8
4000	9.5	9	5.5	5.5	35.5	9.5	-0.5		-5.4
6000	15.5	20.5	2	2	40	17	21		4.3
8000	13	12	0	0	40	17.5	23		12.6
10000	-	-	-	-	-	22	18		13.9
12500	-	-	-	-	-	27.5	27		12.3
14000	-	-	-	-	-	35	33.5		18.4
16000	-	-	-	-	-	56 (-)	45.5		40.2

(*) Calibration of bone vibrator (B71) refers to mastoid placement.

The reference norms are ISO 389-1:2000, ISO 389-2:1997, ISO 389-3:1999, ISO 389-5:2007, ISO 389-8:2004, ISO 389-7:2006 and ANSI S3.6:2010.

REFERENCE EQUIVALENT THRESHOLD LEVEL FOR SPEECH IEC 60645-2 1997					
	TDH39	DD45	ER3 / ER5	B71	Free Field
	Coupler: ANSI S3.7-1995 (NBS-9A) / IEC 60318-3 1998 (6ccm)		IEC 60318-5	IEC 60373	
	dB [re 20 μ Pa]	dB [re 20 μ Pa]	dB [re 20 μ Pa]	dB [re 1 μ N]	dB [re 20 μ Pa]
Linear Type A	20.0	20.0	20.0	55.0	20.0
Equ. FF Type AE	20.0	20.0	-	-	-
For stimulus: LINE, MIC, DIGITAL, SPEECH NOISE, WHITE NOISE					

REFERENCE EQUIVALENT THRESHOLD LEVEL FOR SPEECH ANSI S3.6 2010					
	TDH39	DD45	ER3 / ER5	B71	Free Field
	Coupler: ANSI S3.7-1995 (NBS-9A) / IEC 60318-3 1998 (6ccm)		IEC 60318-5	IEC 60373	refers to 0 deg incidence
	dB [re 20 μ Pa]	dB [re 20 μ Pa]	dB [re 20 μ Pa]	dB [re 1 μ N]	dB [re 20 μ Pa]
Linear Type A	19.5	18.5	12.5	55.0	14.5
Equ. FF Type AE	19.5	18.5	-	-	-
For stimulus: LINE, MIC, DIGITAL, SPEECH NOISE, WHITE NOISE					

APPLICABLE STANDARDS	
Pure Tone Audiometry	EN 60645-1 / ANSI S3.6, Type 1
Speech Audiometry	EN 60645-2 / ANSI S3.6, Type A or A-E (*)
HF Audiometry	EN 60645-4 / ANSI S3.6 (Piano Plus)
Autothreshold	Modified from EN ISO 8253-1:2000
Calibration	AC: EN ISO 389-1 (TDH 39), EN ISO 389-2 (ER-3 and ER-5), EN ISO 389-5 and EN ISO 389-8 (HDA 200), data from the manufacturer (DD45 and HDA 300) BC: EN ISO 389-3 FF: EN ISO 389-7
Electrical safety	EN 60601-1 Class I Type BF
EMC	EN 60601-1-2

(*) Type A-E if the free field equivalent filter for AC output is enabled (see *Chapter 11: Settings* for details)

CE CERTIFICATE	
93/42/EEC MDD classification	Class IIa
Classification rule (Annex IX, 93/42/EEC)	10
Notified body	TÜV SÜD Product Service GmbH Ridlerstrasse 65 D-80339 München Germany
Number of the notified body	0123

APPENDIX B:

Specifications of the amplifier / speakers for free field

In order to reach the values of the intensities for free field output specified in the Appendix A (both for “normal” and “extended” range), the amplifier and the loudspeakers (or the active loudspeakers) must meet the following specs.

Characteristics of the dual channel amplifier:

	Normal range	Extended range
Minimum output power	2 x 60 W rms	2 x 200 W rms
Passband	90 Hz – 20 kHz	

Characteristics of the loudspeakers:

	Normal range	Extended range
Minimum output power	2 x 60 W rms	2 x 200 W rms
Sensitivity (at 1 m for 1 W, 1 kHz)	> 88 dB SPL	> 98 dB SPL
Passband	90 Hz – 20 kHz	



APPENDIX C:

Audiometric symbols

Air Conduction

	Right	Left	Bilateral
HL threshold without masking			
HL threshold with masking			
UCL threshold	  	  	

Bone Conduction

	Right	Left
HL threshold without masking		
HL threshold with masking	 	 

The direction of the symbols used for BC and the symbol used for masked BC can be selected in the device set-up window (see *Chapter 12: Settings*).

Free Field

	Right	Left	Bilateral
HL threshold			

In case of absence of response, a diagonal arrow pointing towards bottom is added in the lower part of the symbol.



APPENDIX D:

Troubleshooting

Problem	Possible cause	Solution
No signal from a transducer	Transducer not connected to the correct output	Connect the transducer to the correct output
	Transducer damaged	Contact Inventis service department or dealer
No signal from patient response button when pressed	Wrong connection	Connect the patient response button to the correct socket
	Patient response button damaged	Contact Inventis service department or dealer
No signal from monitor headphones	Wrong connection	Connect the monitor headphones to the correct socket
	Headphone volume too low	Press the MONITOR button to increase the volume
Patient's voice cannot be heard	Problems with TALKBACK input connection	Check the connection to the TALKBACK input
	TALKBACK volume too low	Adjust the TALKBACK volume control
Connection between PC and audiometer	Problems with USB connection	Check the USB connection between instrument and computer

Problem	Possible cause	Solution
cannot be established	USB cable damaged	Change the USB cable (standard USB A/B cable)
INT input cannot be selected in speech audiometry mode	Internal memory not enabled	Verify that the audiometer model has an internal memory
	No speech material stored in the internal memory	Use <i>ATIT</i> software to check that the internal memory contains speech material
Date and time prompt appears when instrument is powered up	Internal battery failure	Contact Inventis service department or dealer to have the battery replaced
Display remains blank	Instrument not powered up correctly	Check the connection to the power supply and make certain the switch is in position "1"
	Adapter damaged	Contact Inventis service department or dealer
You cannot access to a test	Optional test not enabled	Contact your reference technical service to obtain the licence, communicating the device serial number



Where the audiometer is used in conjunction with a soundproof booth, check that the connections both inside the booth and between the booth and the instrument are correct and secure.

APPENDIX E:

Electromagnetic emissions

Piano has been thoroughly tested and respects the limits for electro-medical devices specified by IEC 60601-1-2 standards. These limits ensure reasonable protection against hazardous interference in typical medical installations.

The instrument generates, uses and radiates radio frequency energy. If not installed and used according to the instructions in this manual, it may interfere with other nearby devices. No guarantee is given that interference will not occur under certain conditions.



Piano should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, Piano should be observed to verify normal operation in the configuration in which it will be used.

The existence of electromagnetic interference can be verified easily by switching the instrument off and back on again. If it is proven that the device is indeed interfering with other devices, try to solve the problem by adopting one of the following solutions:

- change the orientation and/or position of the affected device;
- move the two devices further away from each other;
- contact the manufacturer or authorised service organisation for further assistance.

List of cables, transducers and accessories

Cables, transducers and accessories with which Inventis claims the compliance with the IEC 60601-1-2 standard are those ones supplied with the device, in particular the followings:

- 1) 6Vdc Medical Grade Power Supply
- 2) Power supply cable (maximum length: 1.8 m)
- 3) TDH39 or DD-45 transducers with 2 m double signal shielded cable
- 4) Insert earphones, manufacturer: Etymotic, model: ER-3 / ER-5

- 5) Bone vibrator B-71 transducer with twisted not shielded double signal cable 2m
- 6) IME-100 Insert masking earphone with shielded cable 2m
- 7) HDA200 or HDA300 transducer, manufacturer: Sennheiser, with 2 m double signal shielded cable
- 8) Monitor headset with boom microphone, manufacturer: Sennheiser, model: PC3
- 9) Talk back microphone with 1 m shielded cable
- 10) Patient response switch (manufactured by Inventis) with 2 m shielded cable
- 11) USB cable, shielded, maximum length: 2 m



The use of accessories, transducers and cables other than those specified, except for transducers and cables sold by the manufacturer as spare parts for internal components, may result in increased emissions or decreased immunity of the device.

Anyone connecting additional equipment is responsible for making sure the system complies with the IEC 60601-1-2 standard.

Guidance and manufacturer's declaration – electromagnetic emissions		
Piano is intended for use in the electromagnetic environment specified below. The customer or the user of Piano should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR11	Group 1	Piano uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment. Piano is suitable for use in all establishments including domestic establishment and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flickers emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
Piano is intended for use in the electromagnetic environment specified below. The customer or the user of Piano should assure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	± 2 kV for power supply lines ± 1 kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$< 5\% U_T$ ($> 95\%$ dip in U_T) for 0,5 cycle. $40\% U_T$ (60% dip in U_T) for 5 cycles. $70\% U_T$ (30% dip in U_T) for 25 cycles. $< 5\% U_T$ ($> 95\%$ dip in U_T) for 5 s.	$< 5\% U_T$ ($> 95\%$ dip in U_T) for 0,5 cycle. $40\% U_T$ (60% dip in U_T) for 5 cycles. $70\% U_T$ (30% dip in U_T) for 25 cycles. $< 5\% U_T$ ($> 95\%$ dip in U_T) for 5 s.	Mains power quality should be that of a typical commercial or hospital environment. If the user of Piano requires continued operation during power mains interruptions, it is recommended that Piano be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. main voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

Piano is intended for use in the electromagnetic environment specified below. The customer or the user of Piano should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compl. Level	Electromagnetic environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 Mhz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of Piano, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 Mhz to 2,5 Ghz	3 V/m	$d = 1,2 \sqrt{P}$ 80 MHz to 800MHz $d = 2,3 \sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular / Cordless) telephones and land mobile, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If measured field strength in the location in which Piano is used exceeds the applicable RF

compliance level above, Piano should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Piano.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and Piano			
Piano is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Piano can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Piano as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1,2 \sqrt{P}$	80 MHz to 800 MHz $d = 1,2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3 \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer.			
<i>Note 1:</i> At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
<i>Note 2:</i> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

APPENDIX F:

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